US007792562C1

(12) **EX PARTE REEXAMINATION CERTIFICATE** (8656th)

United States Patent
Shults et al.

(10) **Number: US 7,792,562 C1**
(45) **Certificate Issued: *Nov. 8, 2011**

(54) **DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS**

(75) Inventors: **Mark C. Shults**, Madison, WI (US); **Stuart J. Updike**, Madison, WI (US); **Rathbun K. Rhodes**, Madison, WI (US)

(73) Assignee: **DexCom, Inc.**, San Diego, CA (US)

Reexamination Request:
No. 90/011,466, Jan. 31, 2011

Reexamination Certificate for:

Patent No.:	**7,792,562**
Issued:	**Sep. 7, 2010**
Appl. No.:	**12/645,097**
Filed:	**Dec. 22, 2009**

(*) Notice: This patent is subject to a terminal disclaimer.

Certificate of Correction issued Feb. 22, 2011.

Related U.S. Application Data

(60) Continuation of application No. 09/447,227, filed on Nov. 22, 1999, now Pat. No. 8,027,708, which is a division of application No. 08/811,473, filed on Mar. 4, 1997, now Pat. No. 6,001,067.

(51) **Int. Cl.**
A61B 5/00 (2006.01)

(52) **U.S. Cl.** **600/347**; 600/365

(58) **Field of Classification Search** ..... None
See application file for complete search history.

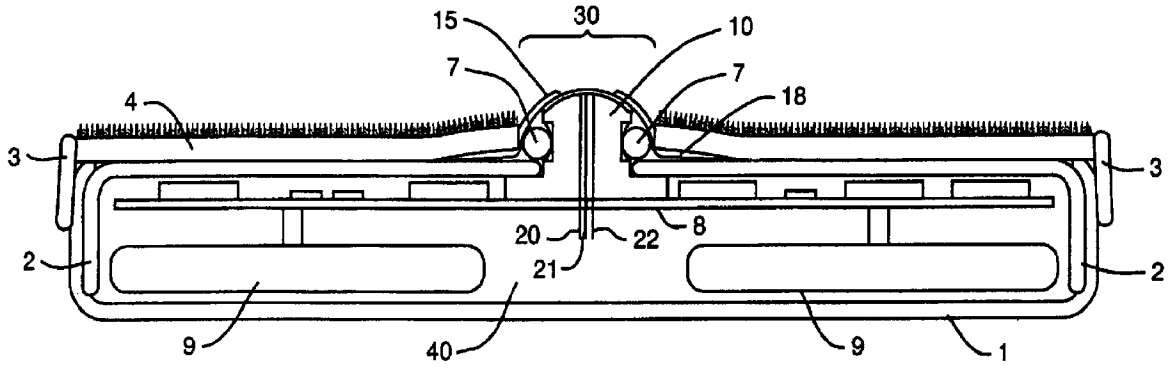
(56) **References Cited**

To view the complete listing of prior art documents cited during the proceeding for Reexamination Control Number 90/011,466, please refer to the USPTO's public Patent Application Information Retrieval (PAIR) system under the Display References tab.

Primary Examiner—Beverly M. Flanagan

(57) **ABSTRACT**

Devices and methods for determining analyte levels are described. The devices and methods allow for the implantation of analyte-monitoring devices, such as glucose monitoring devices, that result in the delivery of a dependable flow of blood to deliver sample to the implanted device. The devices comprise a unique microarchitectural arrangement in the sensor region that allows accurate data to be obtained over long periods of time.



EX PARTE REEXAMINATION CERTIFICATE ISSUED UNDER 35 U.S.C. 307

THE PATENT IS HEREBY AMENDED AS INDICATED BELOW.

Matter enclosed in heavy brackets [ ] appeared in the patent, but has been deleted and is no longer a part of the patent; matter printed in italics indicates additions made to the patent.

AS A RESULT OF REEXAMINATION, IT HAS BEEN DETERMINED THAT:

The patentability of claims **1-27**, **29-31**, **33-35**, **38-41**, **43-46**, **50**, **51**, **54-56**, **58-60**, **63-66**, **68-71**, **75**, **76**, **81-83**, **85-87**, **90-93**, **95-98**, **102**, **103**, **108-110**, **112-119**, **121-124**, **128** and **129** is confirmed.

Claims **28**, **53**, **80** and **107** are cancelled.

Claims **32**, **36**, **42**, **47-49**, **52**, **57**, **61**, **67**, **72-74**, **77-79**, **84**, **88**, **94**, **99-101**, **104-106**, **111**, **120**, **125-127**, **130-132** are determined to be patentable as amended.

Claims **37**, **62** and **89**, dependent on an amended claim, are determined to be patentable.

New claims **133-136** are added and determined to be patentable.

32. The device of claim **[28]***133,* wherein the membrane comprises a layer comprising an enzyme.

36. The device of claim **[28]***133,* wherein the membrane comprises a urethane polymer or a polyurethane.

42. The device of claim **[28]***133,* wherein at least 95% of glucose concentration values measured by the signal are within 25% of an actual value over the period of time, and wherein the actual value is determined by analysis of blood.

47. The device of claim **[28]***133,* wherein the period of time is greater than about 3 days.

48. The device of claim **[28]***133,* wherein the period of time is greater than about 5 days.

49. The device of claim **[28]***133,* wherein the period of time is greater than about 7 days.

52. The device of claim **[28]***133,* wherein the device is configured for single-point recalibration.

57. The device of claim **[53]***134,* wherein the membrane comprises a layer comprising an enzyme.

61. The device of claim **[53]***134,* wherein the membrane comprises a urethane polymer or a polyurethane.

67. The device of claim **[53]***134,* wherein at least 95% of glucose concentration values measured by the signal are within 25% of an actual value over the period of time, and wherein the actual value is determined by analysis of blood.

72. The device of claim **[53]***134,* wherein the period of time is greater than about 3 days.

73. The device of claim **[53]***134,* wherein the period of time is greater than about 5 days.

74. The device of claim **[53]***134,* wherein the period of time is greater than about 7 days.

77. The device of claim **[53]***134,* wherein the device is configured for single-point recalibration.

78. The device of claim **[53]***134,* wherein the device is configured to be implanted in the host.

79. The device of claim **[53]***134,* wherein the device is configured to respond substantially linearly to changes in glucose concentration at a glucose concentration of up to at least about 400 mg/dL.

84. The device of claim **[80]***135,* wherein the membrane comprises a layer comprising an enzyme.

88. The device of claim **[80]***135,* wherein the membrane comprises a urethane polymer or a polyurethane.

94. The device of claim **[80]***135,* wherein at least 95% of glucose concentration values measured by the signal are within 25% of an actual value over the period of time, and wherein the actual value is determined by analysis of blood.

99. The device of claim **[80]***135,* wherein the period of time is greater than about 3 days.

100. The device of claim **[80]***135,* wherein the period of time is geater than about 5 days.

101. The device of claim **[80]***135,* wherein the period of time is greater than about 7 days.

104. The device of claim **[80]***135,* wherein the device is configured for single-point recalibration.

105. The device of claim **[80]***135,* wherein the device is configured to be implanted in the host.

106. The device of claim **[80]***135,* wherein the device is configured to respond substantially linearly to changes in glucose concentration at a glucose concentration of up to at least about 400 mg/dL.

111. The device of claim **[107]***136,* wherein the membrane comprises a layer comprising an enzyme.

120. The device of claim **[107]***136,* wherein at least 95% of glucose concentration values measured by the signal are within 25% of an actual value over the period of time, and wherein the actual value is determined by analysis of blood.

125. The device of claim **[107]***136,* wherein the period of time is greater than about 3 days.

126. The device of claim **[107]***136,* wherein the period of time is greater than about **5** days.

127. The device of claim **[107]***136,* wherein the period of time is greater than about 7 days.

130. The device of claim **[107]***136,* wherein the device configured for single-point recalibration.

131. The device of claim **[107]***136,* wherein the device is congfigured to be implanted in the host.

132. The device of claim **[107]***136,* wherein the device is configured to respond substantially linearly to changes in glucose concentration at a glucose concentration of up to at least about 400 mg/dL.

133. A device for measuring a glucose concentration in a host, the device comprising:

an electrode surface operably to an electronic circuit and configured to continuously measure a signal indicative of a glucose concentration in a subcutaneous tissue of a host for a period of time of continuous glucose sensing; and

a membrane located over at least a portion of the electrode surface, wherein the membrane is configured to control a flux of oxygen and glucose;

wherein the device is capable of exhibiting, at a glucose concentration of about 400 mg/dL, no more than a 10% drop in sensor output over a range of pO_2 from about 150 mm Hg down to about 30 mm Hg; and wherein the device is configured to be implanted in the host, whereby at least 95% of glucose concentration values measured by the signal are within 25% of corresponding reference values obtained periodically throughout the continuous glucose sensing, and wherein the plurality of references values are determined by analysis of blood.

134. A device for measuring a glucose concentration in a host, the device comprising:

a sensor operably connected to an electronic circuit and configured to continuously measure a signal indicative of a glucose concentration in a host for a period of time; and

a membrane located over at least a portion of the sensor, wherein the membrane is configured to control a flux of oxygen and glucose;

wherein the device is capable of exhibiting, at a glucose concentration of about 400 mg/dL, no more than a 10% drop in sensor output over a range of pO_2 from about 150 mm Hg down to about 30 mm Hg; and wherein the device is configured to respond substantially linearly to changes in glucose concentration at a glucose concentration of up to at least about 400 mg/dL, wherein the device is configured to prevent motion artifact.

135. A device for measuring a glucose concentration in a host, the device comprising:

a sensor operably connected to an electronic circuit and configured to continuously measure a signal indicative of a glucose concentration in a host for a period of time; and

a membrane located over at least a portion of the sensor, wherein the membrane comprises a cross-linked polymer and is configured to control a flux of oxygen and glucose;

wherein the device is capable of exhibiting, at a glucose concentration of about 400 mg/dL, no more than a 10% drop in sensor output over a range of pO_2 from about 150 mm Hg down to about 30 mm Hg, and wherein the device is capable of attaining a 90% time response to a 100 mg/dL glucose concentration step in less than 5 minutes.

136. A device for measuring a glucose concentration in a host, the device comprising:

a sensor operably connected to an electronic circuit and configured to continuously measure a signal indicative of a glucose concentration in a host for a period of time; and

a membrane located over at least a portion of the sensor, wherein the membrane comprises a polyurethane or urethane polymer and is configured to control a flux of oxygen and glucose, wherein the membrane is further configured to block interfering species;

wherein the device is capable of exhibiting, at a glucose concentration of about 400 mg/dL, no more than a 10% drop in sensor output over a range of pO_2 from about 150 mm Hg down to about 30 mm Hg.

* * * * *

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
90/011,466	01/31/2011	7792562	DEXCOM.8D1C3X	8367

68851 7590 09/14/2011

KNOBBE, MARTENS, OLSEN & BEAR, LLP
2040 MAIN STREET
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IRVINE, CA 92614

EXAMINER	
ART UNIT	PAPER NUMBER

DATE MAILED: 09/14/2011

Please find below and/or attached an Office communication concerning this application or proceeding.

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East Palo Alto, CA 94303

EX PARTE REEXAMINATION COMMUNICATION TRANSMITTAL FORM

REEXAMINATION CONTROL NO. *90/011,466*.

PATENT NO. *7792562*.

ART UNIT *3993*.

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified *ex parte* reexamination proceeding (37 CFR 1.550(f)).

Where this copy is supplied after the reply by requester, 37 CFR 1.535, or the time for filing a reply has passed, no submission on behalf of the *ex parte* reexamination requester will be acknowledged or considered (37 CFR 1.550(g)).

Notice of Intent to Issue Ex Parte Reexamination Certificate	Control No.	Patent Under Reexamination
	90/011,466	7792562
	Examiner	Art Unit
	BEVERLY FLANAGAN	3993

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

1. ☒ Prosecution on the merits is (or remains) closed in this *ex parte* reexamination proceeding. This proceeding is subject to reopening at the initiative of the Office or upon petition. *Cf.* 37 CFR 1.313(a). A Certificate will be issued in view of
   - (a) ☒ Patent owner's communication(s) filed: *20 June 2011*.
   - (b) ☐ Patent owner's late response filed: _____.
   - (c) ☐ Patent owner's failure to file an appropriate response to the Office action mailed: _____.
   - (d) ☐ Patent owner's failure to timely file an Appeal Brief (37 CFR 41.31).
   - (e) ☐ Other: _____.

   Status of *Ex Parte* Reexamination:
   - (f) Change in the Specification: ☐ Yes ☒ No
   - (g) Change in the Drawing(s): ☐ Yes ☒ No
   - (h) Status of the Claim(s):
     - (1) Patent claim(s) confirmed: *1-27,29-31,33-35,38-41,43-46,50,51,54-56,58-60 and 63-66*.
     - (2) Patent claim(s) amended (including dependent on amended claim(s)): *32,36,37,42,47-49,52*
     - (3) Patent claim(s) canceled: *28,53,80 and 107*.
     - (4) Newly presented claim(s) patentable: 133-136.
     - (5) Newly presented canceled claims: _____.
     - (6) Patent claim(s) ☐ previously ☐ currently disclaimed: _____
     - (7) Patent claim(s) not subject to reexamination: _____.

2. ☒ Note the attached statement of reasons for patentability and/or confirmation. Any comments considered necessary by patent owner regarding reasons for patentability and/or confirmation must be submitted promptly to avoid processing delays. Such submission(s) should be labeled: "Comments On Statement of Reasons for Patentability and/or Confirmation."

3. ☐ Note attached NOTICE OF REFERENCES CITED (PTO-892).

4. ☒ Note attached LIST OF REFERENCES CITED (PTO/SB/08 or PTO/SB/08 substitute).

5. ☐ The drawing correction request filed on _____ is: ☐ approved ☐ disapproved.

6. ☐ Acknowledgment is made of the priority claim under 35 U.S.C. § 119(a)-(d) or (f).
   a)☐ All b)☐ Some* c)☐ None of the certified copies have
   - ☐ been received.
   - ☐ not been received.
   - ☐ been filed in Application No. _____.
   - ☐ been filed in reexamination Control No. _____.
   - ☐ been received by the International Bureau in PCT Application No. _____.

   * Certified copies not received: _____.

7. ☒ Note attached Examiner's Amendment.

8. ☐ Note attached Interview Summary (PTO-474).

9. ☐ Other: _____.

cc: Requester (if third party requester)

90/011,466

Continuation Sheet (PTOL-469) **Reexam Control No.**

Continuation from 1(h)(1): 68-71,75,76,81-83,85-87,90-93,95-98,102,103,108-110,112-119,121-124,128, and 129.

Continuation from 1(h)(2): 57,61,62,67,72-74,77-79,84,88,89,94,99-101,104-106,111,120,125-127, and 130-132.

Claims Patentable and Confirmed

Claims 1-27, 29-31, 33-35, 37-41, 43-46, 50-51, 54-56, 58-60, 62-66, 68-71, 75, 76, 81-83, 85-87, 89-93, 95-98, 102, 103, 108-110, 112-115, 121-124, 128 and 129 are confirmed. Claims 32, 36, 42, 47-49, 52, 57, 61, 67, 72-74, 77-79, 84, 88, 94, 99-101, 104-106, 111, 120, 125-127 and 130-132 are patentable as amended. Newly filed claims 133-136 are patentable. Claims 28, 53, 80 and 107 are canceled.

STATEMENT OF REASONS FOR PATENTABILITY AND/OR CONFIRMATION

The following is an examiner's statement of reasons for patentability and/or confirmation of the claims found patentable in this reexamination proceeding: The prior art does not teach or fairly address the invention as recited in claims 1-22, 24-52, 54-79, 81-106 and 108-136 of U.S. Patent No. 7,792,562. Specifically, the examiner agrees with patent owner that the applied prior art reference Allen does not teach an *in vitro* sensing device and does not teach a device with a membrane comprising a cross-linked polymer. The examiner also agrees that Kusano is not configured to use oxygen from surrounding biological fluid, but instead uses oxygen from ambient air and thus is not capable of exhibiting, at a glucose concentration of about 400 mg/dL, no more than a 10% drop in sensor output over a range of pO_2 from about 150 mm Hg down to about 30 mm Hg. Claims 1-22, 24-52, 54-79, 81-106 and 108-136 are thus patentable.

Any comments considered necessary by PATENT OWNER regarding the above statement must be submitted promptly to avoid processing delays. Such submission by

the patent owner should be labeled: "Comments on Statement of Reasons for Patentability and/or Confirmation" and will be placed in the reexamination file.

Conclusion

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Central Reexamination Unit

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401 Dulaney Street
Alexandria, VA 22314

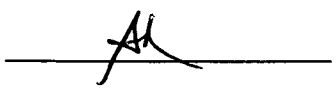
Any inquiry concerning this communication or earlier communications from the Examiner, or as to the status of this proceeding, should be directed to the Central Reexamination Unit at telephone number (571) 272-7705.

Signed:

/Beverly M. Flanagan/

Beverly M. Flanagan
CRU Examiner
GAU 3993
(571) 272-4766

Conferee /JRJ/

Conferee 

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT		
	Reexam Control No.	90/011466
	Filing Date	01-31-2011
	First Named Inventor	Shults, Mark C.
	Art Unit	3993
(Multiple sheets used when necessary)	Examiner	Flanagan, Beverly M.
SHEET 1 OF 2	Attorney Docket No.	DEXCOM.8D1C3X

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
/B.F./	1	4,273,636	06-16-1981	Shimada et al.	
/B.F./	2	4,340,458	07-20-1982	Lerner et al.	
/B.F./	3	5,464,013	11-07-1995	Lemelson, Jerome H.	
/B.F./	4	5,508,030	04-16-1996	Bierman	
/B.F./	5	5,589,498	12-31-1996	Mohr et al.	
/B.F./	6	5,906,817	05-25-1999	Moullier et al.	
/B.F./	7	6,406,426	06-18-2002	Reuss et al.	
/B.F./	8	6,558,321	05-06-2003	Burd et al.	
/B.F./	9	6,666,821	12-23-2003	Keimel, John G.	
/B.F./	10	6,991,643	01-31-2006	Saadat	
/B.F./	11	7,711,402	05-04-2010	Shults, Mark et al.	
/B.F./	12	7,835,777	11-16-2010	Shults, Mark et al.	
/B.F./	13	2010-0099970	04-22-2010	Shults et al.	
/B.F./	14	2010-0099971	04-22-2010	Shults et al.	
/B.F./	15	2010-0160760	06-24-2010	Shults et al.	
/B.F./	16	2010-0204559	08-12-2010	Shults et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.	Foreign Patent Document *Country Code-Number-Kind Code* Example: JP 1234567 A1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T[1]

NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[1]
/B.F./	17	JOBST et al., Thin-Film Microbiosensors for Glucose-Lactate Monitoring, Anal Chem. (1996) 68(18): 3173-3179	
/B.F./	18	International Preliminary Examination Report dated June 4, 2003 in PCT/US2001/23850, filed 07/30/2001	
/B.F./	19	International Search Report dated January 16, 2002 in PCT/US2001/23850, filed 07/30/2001	

Examiner Signature	/Beverly Flanagan/	Date Considered	09/12/2011

***Examiner:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

T[1] - Place a check mark in this area when an English language Translation is attached.

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Reexam Control No.	90/011466
	Filing Date	01-31-2011
	First Named Inventor	Shults, Mark C.
	Art Unit	3993
(Multiple sheets used when necessary)	Examiner	Flanagan, Beverly M.
SHEET 2 OF 2	Attorney Docket No.	DEXCOM.8D1C3X

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[1]
/B.F./	20	International Search Report dated July 9, 1998 in PCT/US1998/04090, filed 03/03/1998	
/B.F./	21	Electronic File History of ex parte Reexamination Control No. 90/011,345, filed 11/19/2010 containing Office Action(s) dated 12/16/2010 and 01/12/2011, and Applicant(s) Response filed 03/14/2011 as of March 24, 2011.	Uploaded in 2 parts

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Examiner Signature	/Beverly Flanagan/	Date Considered	09/12/2011

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PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Reexam Control No.	90/011466
	Filing Date	01-31-2011
	First Named Inventor	Shults, Mark C.
	Art Unit	3993
(Multiple sheets used when necessary)	Examiner	Flanagan, Beverly M.
SHEET 1 OF 1	Attorney Docket No.	DEXCOM.8D1C3X

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[1]
BF	1	SAMUELS, M. P. "The effects of flight and altitude" *Arch Dis Child* 2004;**89**:448–455.	

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032411
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Examiner Signature	B. FLANAGAN	Date Considered	9/2/11

***Examiner:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Ex Parte Reexamination Interview Summary	Control No.	Patent Under Reexamination	
	90/011,466	7792562	
	Examiner	Art Unit	
	BEVERLY FLANAGAN	3993	

All participants (USPTO personnel, patent owner, patent owner's representative):

(1) *BEVERLY FLANAGAN*

(2) *SPE Andres Kashnikow*

(3) *Exr. David Reip*

(4) *Kaare Larson; Laura Johnson*

Date of Interview: *19 May 2011*

Type: a)☐ Telephonic b)☐ Video Conference
c)☒ Personal (copy given to: 1)☐ patent owner 2)☒ patent owner's representative)

Exhibit shown or demonstration conducted: d)☐ Yes e)☒ No.
If Yes, brief description: _____

Agreement with respect to the claims f)☐ was reached. g)☒ was not reached. h)☐ N/A.
Any other agreement(s) are set forth below under "Description of the general nature of what was agreed to..."

Claim(s) discussed: *28,53,80 and 107*.

Identification of prior art discussed: *Kusano and Allen (of record)*.

Description of the general nature of what was agreed to if an agreement was reached, or any other comments:
Patent owner argued that Kusano does not teach a sensor capable of exhibiting no more than a 10% drop in sensor output. Patent owner also argued that neither Allen nor Kusano teaches an in vitro calibration factor. Amendments to follow..

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims patentable, if available, must be attached. Also, where no copy of the amendments that would render the claims patentable is available, a summary thereof must be attached.)

A FORMAL WRITTEN RESPONSE TO THE LAST OFFICE ACTION MUST INCLUDE PATENT OWNER'S STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. (See MPEP § 2281). IF A RESPONSE TO THE LAST OFFICE ACTION HAS ALREADY BEEN FILED, THEN PATENT OWNER IS GIVEN **ONE MONTH** FROM THIS INTERVIEW DATE TO PROVIDE THE MANDATORY STATEMENT OF THE SUBSTANCE OF THE INTERVIEW (37 CFR 1.560(b)). THE REQUIREMENT FOR PATENT OWNER'S STATEMENT CAN NOT BE WAIVED. **EXTENSIONS OF TIME ARE GOVERNED BY 37 CFR 1.550(c).**

cc: Requester (if third party requester)

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Reexam Control No.	90/011466
	Filing Date	01-31-2011
	First Named Inventor	Shults, Mark C.
	Art Unit	3993
(Multiple sheets used when necessary)	Examiner	Flanagan, Beverly M.
SHEET 1 OF 1	Attorney Docket No.	DEXCOM.8D1C3X

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T^1
	1	SAMUELS, M. P. "The effects of flight and altitude" *Arch Dis Child* 2004;**89**:448–455.	

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061711

Examiner Signature	Date Considered
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent	:	US 7,792,562
Reexam. No	:	90/011,466
Filed	:	1/31/2011
For	:	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS
Examiner	:	Flanagan, Beverly
Art Unit	:	3993
Conf No.	:	8367

AMENDMENT

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P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Office Action dated April 18, 2011, for which a response is due on June 20, 2011, Patent Owner herewith submits a response and respectfully requests reconsideration and allowance of the pending claims in light of the remarks presented herein.

Amendment to the Claims begins on page 2 of this paper.

Summary of Interview begins on page 14 of this paper.

Claim Status and Support for Amendments begins on page 15 of this paper.

Remarks begin on page 22 of this paper.

AMENDMENT TO THE CLAIMS

1. (Original) A device for measuring a glucose concentration in a host, the device comprising:

a sensor operably connected to an electronic circuit and configured to continuously measure a signal indicative of a glucose concentration in a host for a period of time; and

a membrane located over at least a portion of the sensor, wherein the membrane is configured to control a flux of oxygen and glucose;

wherein the device is capable of exhibiting, at a glucose concentration of about 400 mg/dL, no more than a 10% drop in sensor output over a range of pO_2 from about 150 mm Hg down to about 30 mm Hg, and wherein the device is configured to use an *in vitro* calibration factor for initial calibration.

2. (Original) The device of claim 1, wherein the sensor comprises a first electrode formed at least in part from a platinum wire.

3. (Original) The device of claim 2, wherein the sensor further comprises a second electrode formed at least in part from a silver wire.

4. (Original) The device of claim 3, wherein the membrane is located over the first electrode and the second electrode.

5. (Original) The device of claim 1, wherein the membrane comprises a layer comprising an enzyme.

6. (Original) The device of claim 1, wherein the membrane comprises an electrolyte layer.

7. (Original) The device of claim 1, wherein the membrane comprises a water-swellable film.

8. (Original) The device of claim 1, wherein the membrane comprises polyvinylpyrrolidone.

9. (Original) The device of claim 1, wherein the membrane comprises a urethane polymer or a polyurethane.

10. (Original) The device of claim 9, wherein the urethane polymer or polyurethane comprises a polycarbonate-polyurethane backbone.

11. (Original) The device of claim 1, wherein the membrane comprises a block copolymer.

12. (Original) The device of claim 1, wherein the membrane comprises a block copolyurethaneurea.

13. (Original) The device of claim 1, wherein the membrane comprises a layer that is configured to control the flux of oxygen and glucose and that is monolithic and homogeneous.

14. (Original) The device of claim 1, wherein the membrane comprises a layer that is configured to control the flux of oxygen and glucose and that is monolithic and heterogeneous.

15. (Original) The device of claim 1, wherein at least 95% of glucose concentration values measured by the signal are within 25% of an actual value over the period of time, and wherein the actual value is determined by analysis of blood.

16. (Original) The device of claim 1, wherein the device is configured to respond substantially linearly to changes in glucose concentration at a glucose concentration of up to about 500 mg/dL.

17. (Original) The device of claim 1, wherein the membrane has a thickness of from about 15 microns to about 60 microns.

18. (Original) The device of claim 1, wherein the membrane has a thickness of from about 20 microns to about 60 microns.

19. (Original) The device of claim 1, wherein the membrane has a thickness of from about 40 microns to about 60 microns.

20. (Original) The device of claim 1, wherein the period of time is greater than about 3 days.

21. (Original) The device of claim 1, wherein the period of time is greater than about 5 days.

22. (Original) The device of claim 1, wherein the period of time is greater than about 7 days.

23. (Original) The device of claim 1, wherein an offset current defined by a current at 0 mg/dL remains stable during a period of time of continuous measurement of the glucose concentration in the host.

24. (Original) The device of claim 1, wherein the device is capable of obtaining a calibration stability that is maintained within 10% for one week.

25. (Original) The device of claim 1, wherein the device is configured for single-point recalibration.

26. (Original) The device of claim 1, wherein the device is configured to be implanted in the host.

27. (Original) The device of claim 1, wherein the device is configured to respond substantially linearly to changes in glucose concentration at a glucose concentration of up to at least about 400 mg/dL.

28. (Canceled)

29. (Original) The device of claim 28, wherein the device comprises a first electrode formed at least in part from a platinum wire.

30. (Original) The device of claim 29, wherein the device further comprises a second electrode formed at least in part from a silver wire.

31. (Original) The device of claim 30, wherein the membrane is located over the first electrode and the second electrode.

32. (Currently Amended) The device of claim 133 [28], wherein the membrane comprises a layer comprising an enzyme.

33. (Original) The device of claim 28, wherein the membrane comprises an electrolyte layer.

34. (Original) The device of claim 28, wherein the membrane comprises a water-swellable film.

35. (Original) The device of claim 28, wherein the membrane comprises polyvinylpyrrolidone.

36. (Currently Amended) The device of claim 133 [28], wherein the membrane comprises a urethane polymer or a polyurethane.

37. (Original) The device of claim 36, wherein the urethane polymer or polyurethane comprises a polycarbonate-polyurethane backbone.

38. (Original) The device of claim 28, wherein the membrane comprises a block copolymer.

39. (Original) The device of claim 28, wherein the membrane comprises a block copolyurethaneurea.

40. (Original) The device of claim 28, wherein the membrane comprises a layer that is configured to control the flux of oxygen and glucose and that is monolithic and homogeneous.

41. (Original) The device of claim 28, wherein the membrane comprises a layer that is configured to control the flux of oxygen and glucose and that is monolithic and heterogeneous.

42. (Currently Amended) The device of claim 133 [28], wherein at least 95% of glucose concentration values measured by the signal are within 25% of an actual value over the period of time, and wherein the actual value is determined by analysis of blood.

43. (Original) The device of claim 28, wherein the device is configured to respond substantially linearly to changes in glucose concentration at a glucose concentration of up to about 500 mg/dL.

44. (Original) The device of claim 28, wherein the membrane has a thickness of from about 15 microns to about 60 microns.

45. (Original) The device of claim 28, wherein the membrane has a thickness of from about 20 microns to about 60 microns.

46. (Original) The device of claim 28, wherein the membrane has a thickness of from about 40 microns to about 60 microns.

47. (Currently Amended) The device of claim 133 [28], wherein the period of time is greater than about 3 days.

48. (Currently Amended) The device of claim 133 [28], wherein the period of time is greater than about 5 days.

49. (Currently Amended) The device of claim 133 [28], wherein the period of time is greater than about 7 days.

50. (Original) The device of claim 28, wherein an offset current defined by a current at 0 mg/dL remains stable during a period of time of continuous measurement of the glucose concentration in the host.

51. (Original) The device of claim 28, wherein the device is capable of obtaining a calibration stability that is maintained within 10% for one week.

52. (Currently Amended) The device of claim 133 [28], wherein the device is configured for single-point recalibration.

53. (Canceled)

54. (Original) The device of claim 53, wherein the device comprises a first electrode formed at least in part from a platinum wire.

55. (Original) The device of claim 54, wherein the device further comprises a second electrode formed at least in part from a silver wire.

56. (Original) The device of claim 55, wherein the membrane is located over the first electrode and the second electrode.

57. (Currently Amended) The device of claim 134 [53], wherein the membrane comprises a layer comprising an enzyme.

58. (Original) The device of claim 53, wherein the membrane comprises an electrolyte layer.

59. (Original) The device of claim 53, wherein the membrane comprises a water-swellable film.

60. (Original) The device of claim 53, wherein the membrane comprises polyvinylpyrrolidone.

61. (Currently Amended) The device of claim 134 [53], wherein the membrane comprises a urethane polymer or a polyurethane.

62. (Original) The device of claim 61, wherein the urethane polymer or polyurethane comprises a polycarbonate-polyurethane backbone.

63. (Original) The device of claim 53, wherein the membrane comprises a block copolymer.

64. (Original) The device of claim 53, wherein the membrane comprises a block copolyurethaneurea.

65. (Original) The device of claim 53, wherein the membrane comprises a layer that is configured to control the flux of oxygen and glucose and that is monolithic and homogeneous.

66. (Original) The device of claim 53, wherein the membrane comprises a layer that is configured to control the flux of oxygen and glucose and that is monolithic and heterogeneous.

67. (Currently Amended) The device of claim 134 [53], wherein at least 95% of glucose concentration values measured by the signal are within 25% of an actual value over the period of time, and wherein the actual value is determined by analysis of blood.

68. (Original) The device of claim 53, wherein the device is configured to respond substantially linearly to changes in glucose concentration at a glucose concentration of up to about 500 mg/dL.

69. (Original) The device of claim 53, wherein the membrane has a thickness of from about 15 microns to about 60 microns.

70. (Original) The device of claim 53, wherein the membrane has a thickness of from about 20 microns to about 60 microns.

71. (Original) The device of claim 53, wherein the membrane has a thickness of from about 40 microns to about 60 microns.

72. (Currently Amended) The device of claim 134 [53], wherein the period of time is greater than about 3 days.

73. (Currently Amended) The device of claim 134 [53], wherein the period of time is greater than about 5 days.

74. (Currently Amended) The device of claim 134 [53], wherein the period of time is greater than about 7 days.

75. (Original) The device of claim 53, wherein an offset current defined by a current at 0 mg/dL remains stable during a period of time of continuous measurement of the glucose concentration in the host.

76. (Original) The device of claim 53, wherein the device is capable of obtaining a calibration stability that is maintained within 10% for one week.

77. (Currently Amended) The device of claim 134 [53], wherein the device is configured for single-point recalibration.

78. (Currently Amended) The device of claim 134 [53], wherein the device is configured to be implanted in the host.

79. (Currently Amended) The device of claim 134 [53], wherein the device is configured to respond substantially linearly to changes in glucose concentration at a glucose concentration of up to at least about 400 mg/dL.

80. (Canceled)

81. (Original) The device of claim 80, wherein the device comprises a first electrode formed at least in part from a platinum wire.

82. (Original) The device of claim 81, wherein the device further comprises a second electrode formed at least in part from a silver wire.

83. (Original) The device of claim 82, wherein the membrane is located over the first electrode and the second electrode.

84. (Currently Amended) The device of claim 135 [80], wherein the membrane comprises a layer comprising an enzyme.

85. (Original) The device of claim 80, wherein the membrane comprises an electrolyte layer.

86. (Original) The device of claim 80, wherein the membrane comprises a water-swellable film.

87. (Original) The device of claim 80, wherein the membrane comprises polyvinylpyrrolidone.

88. (Currently Amended) The device of claim 135 [80], wherein the membrane comprises a urethane polymer or a polyurethane.

89. (Original) The device of claim 88, wherein the urethane polymer or polyurethane comprises a polycarbonate-polyurethane backbone.

90. (Original) The device of claim 80, wherein the membrane comprises a block copolymer.

91. (Original) The device of claim 80, wherein the membrane comprises a block copolyurethaneurea.

92. (Original) The device of claim 80, wherein the membrane comprises a layer that is configured to control the flux of oxygen and glucose and that is monolithic and homogeneous.

93. (Original) The device of claim 80, wherein the membrane comprises a layer that is configured to control the flux of oxygen and glucose and that is monolithic and heterogeneous.

94. (Currently Amended) The device of claim 135 [80], wherein at least 95% of glucose concentration values measured by the signal are within 25% of an actual value over the period of time, and wherein the actual value is determined by analysis of blood.

95. (Original) The device of claim 80, wherein the device is configured to respond substantially linearly to changes in glucose concentration at a glucose concentration of up to about 500 mg/dL.

96. (Original) The device of claim 80, wherein the membrane has a thickness of from about 15 microns to about 60 microns.

97. (Original) The device of claim 80, wherein the membrane has a thickness of from about 20 microns to about 60 microns.

98. (Original) The device of claim 80, wherein the membrane has a thickness of from about 40 microns to about 60 microns.

99. (Currently Amended) The device of claim 135 [80], wherein the period of time is greater than about 3 days.

100. (Currently Amended) The device of claim 135 [80], wherein the period of time is greater than about 5 days.

101. (Currently Amended) The device of claim 135 [80], wherein the period of time is greater than about 7 days.

102. (Original) The device of claim 80, wherein an offset current defined by a current at 0 mg/dL remains stable during a period of time of continuous measurement of the glucose concentration in the host.

103. (Original) The device of claim 80, wherein the device is capable of obtaining a calibration stability that is maintained within 10% for one week.

104. (Currently Amended) The device of claim 135 [80], wherein the device is configured for single-point recalibration.

105. (Currently Amended) The device of claim 135 [80], wherein the device is configured to be implanted in the host.

106. (Currently Amended) The device of claim 135 [80], wherein the device is configured to respond substantially linearly to changes in glucose concentration at a glucose concentration of up to at least about 400 mg/dL.

107. (Canceled)

108. (Original) The device of claim 107, wherein the device comprises a first electrode formed at least in part from a platinum wire.

109. (Original) The device of claim 108, wherein the device further comprises a second electrode formed at least in part from a silver wire.

110. (Original) The device of claim 109, wherein the membrane is located over the first electrode and the second electrode.

111. (Currently Amended) The device of claim 136 [107], wherein the membrane comprises a layer comprising an enzyme.

112. (Original) The device of claim 107, wherein the membrane comprises an electrolyte layer.

113. (Original) The device of claim 107, wherein the membrane comprises a water-swellable film.

114. (Original) The device of claim 107, wherein the membrane comprises polyvinylpyrrolidone.

115. (Original) The device of claim 107, wherein the urethane polymer or polyurethane comprises a polycarbonate-polyurethane backbone.

116. (Original) The device of claim 107, wherein the membrane comprises a block copolymer.

117. (Original) The device of claim 107, wherein the membrane comprises a block copolyurethaneurea.

118. (Original) The device of claim 107, wherein the membrane comprises a layer that is configured to control the flux of oxygen and glucose and that is monolithic and homogeneous.

119. (Original) The device of claim 107, wherein the membrane comprises a layer that is configured to control the flux of oxygen and glucose and that is monolithic and heterogeneous.

120. (Currently Amended) The device of claim 136 [107], wherein at least 95% of glucose concentration values measured by the signal are within 25% of an actual value over the period of time, and wherein the actual value is determined by analysis of blood.

121. (Original) The device of claim 107, wherein the device is configured to respond substantially linearly to changes in glucose concentration at a glucose concentration of up to about 500 mg/dL.

122. (Original) The device of claim 107, wherein the membrane has a thickness of from about 15 microns to about 60 microns.

123. (Original) The device of claim 107, wherein the membrane has a thickness of from about 20 microns to about 60 microns.

124. (Original) The device of claim 107, wherein the membrane has a thickness of from about 40 microns to about 60 microns.

125. (Currently Amended) The device of claim 136 [107], wherein the period of time is greater than about 3 days.

126. (Currently Amended) The device of claim 136 [107], wherein the period of time is greater than about 5 days.

127. (Currently Amended) The device of claim 136 [107], wherein the period of time is greater than about 7 days.

128. (Original) The device of claim 107, wherein an offset current defined by a current at 0 mg/dL remains stable during a period of time of continuous measurement of the glucose concentration in the host.

129. (Original) The device of claim 107, wherein the device is capable of obtaining a calibration stability that is maintained within 10% for one week.

130. (Currently Amended) The device of claim 136 [107], wherein the device is configured for single-point recalibration.

131. (Currently Amended) The device of claim 136 [107], wherein the device is configured to be implanted in the host.

132. (Currently Amended) The device of claim 136 [107], wherein the device is configured to respond substantially linearly to changes in glucose concentration at a glucose concentration of up to at least about 400 mg/dL.

133. (New) A device for measuring a glucose concentration in a host, the device comprising:

an electrode surface operably connected to an electronic circuit and configured to continuously measure a signal indicative of a glucose concentration in a subcutaneous tissue of a host for a period of time of continuous glucose sensing; and

a membrane located over at least a portion of the electrode surface, wherein the membrane is configured to control a flux of oxygen and glucose;

wherein the device is capable of exhibiting, at a glucose concentration of about 400 mg/dL, no more than a 10% drop in sensor output over a range of pO_2 from about 150 mm Hg down to about 30 mm Hg; and wherein the device is configured to be implanted in the host, whereby at least 95% of glucose concentration values measured by the signal are within 25% of corresponding reference values obtained periodically throughout the continuous glucose sensing, and wherein the plurality of reference values are determined by analysis of blood.

134. (New) A device for measuring a glucose concentration in a host, the device comprising:

a sensor operably connected to an electronic circuit and configured to continuously measure a signal indicative of a glucose concentration in a host for a period of time; and

a membrane located over at least a portion of the sensor, wherein the membrane is configured to control a flux of oxygen and glucose;

wherein the device is capable of exhibiting, at a glucose concentration of about 400 mg/dL, no more than a 10% drop in sensor output over a range of pO_2 from about 150 mm Hg down to about 30 mm Hg; and wherein the device is configured to respond substantially linearly to changes in glucose concentration at a glucose concentration of up to at least about 400 mg/dL, wherein the device is configured to prevent motion artifact.

135. (New) A device for measuring a glucose concentration in a host, the device comprising:

a sensor operably connected to an electronic circuit and configured to continuously measure a signal indicative of a glucose concentration in a host for a period of time; and

a membrane located over at least a portion of the sensor, wherein the membrane comprises a cross-linked polymer and is configured to control a flux of oxygen and glucose;

wherein the device is capable of exhibiting, at a glucose concentration of about 400 mg/dL, no more than a 10% drop in sensor output over a range of pO_2 from about 150 mm Hg down to about 30 mm Hg; and wherein the device is capable of attaining a 90% time response to a 100 mg/dL glucose concentration step in less than 5 minutes.

136. (New) A device for measuring a glucose concentration in a host, the device comprising:

a sensor operably connected to an electronic circuit and configured to continuously measure a signal indicative of a glucose concentration in a host for a period of time; and

a membrane located over at least a portion of the sensor, wherein the membrane comprises a polyurethane or urethane polymer and is configured to control a flux of oxygen and glucose, wherein the membrane is further configured to block interfering species;

wherein the device is capable of exhibiting, at a glucose concentration of about 400 mg/dL, no more than a 10% drop in sensor output over a range of pO_2 from about 150 mm Hg down to about 30 mm Hg.

SUMMARY OF INTERVIEW

Attendees, Date and Type of Interview

The personal interview was conducted on May 19, 2011 and attended by Examiners Beverly Flangan, David Reip, and Andy Kashnikow, and Patent Owner's representatives Laura Johnson, Kaare Larson, and Paul Lee (via telephone).

Exhibits and/or Demonstrations

N/A.

Identification of Claims Discussed

Claims 28, 53, 80, and 107 of U.S. Patent No. 7,792,562 ("the '562 Patent").

Identification of Art Discussed

U.S. Patent No. 5,322,063 ("Allen") and Kusano, H., Glucose enzyme electrode with percutaneous interface which operates independently of dissolved oxygen, *Clin. Phys. Physiol. Meas.*, vol. 10, 1:1-9 (1989) ("Kusano").

Proposed Amendments, Principal Arguments, Results of Interview, and Other Matters

Patent Owner's representatives and the Examiners discussed whether Allen disclosed a sensor capable of exhibiting, at a glucose concentration of about 400 mg/dL, no more than a 10% drop in sensor output over a range of pO_2 from about 150 mm Hg down to about 30 mm Hg. No agreement was reached. Patent Owner's representatives explained (and the Examiners agreed) that Kusano does not disclose a sensor capable of exhibiting the above-described limitation. Furthermore, Patent Owner's representative explained (and the Examiners agreed) that neither Allen nor Kusano teaches the limitation "wherein the device is configured to use an *in vitro* calibration factor for initial calibration," as recited in Claim 1 of the '562 Patent. The Examiners agreed to consider the arguments in a formal response.

CLAIM STATUS AND SUPPORT FOR AMENDMENTS (37 CFR 1.530(e))

1. **Pending – Unchanged.**
2. **Pending – Unchanged.**
3. **Pending – Unchanged.**
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8. **Pending – Unchanged.**
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23. **Pending – Unchanged.**
24. **Pending – Unchanged.**
25. **Pending – Unchanged.**
26. **Pending – Unchanged.**
27. **Pending – Unchanged.**
28. **Canceled.**
29. **Pending – Unchanged.**

30. **Pending – Unchanged.**

31. **Pending – Unchanged.**

32. **Pending – Amended.** Claim 32 has been amended to depend from new Claim 133.

33. **Pending – Unchanged.**

34. **Pending – Unchanged.**

35. **Pending – Unchanged.**

36. **Pending – Amended.** Claim 36 has been amended to depend from new Claim 133.

37. **Pending – Unchanged.**

38. **Pending – Unchanged.**

39. **Pending – Unchanged.**

40. **Pending – Unchanged.**

41. **Pending – Unchanged.**

42. **Pending – Amended.** Claim 42 has been amended to depend from new Claim 133.

43. **Pending – Unchanged.**

44. **Pending – Unchanged.**

45. **Pending – Unchanged.**

46. **Pending – Unchanged.**

47. **Pending – Amended.** Claim 47 has been amended to depend from new Claim 133.

48. **Pending – Amended.** Claim 48 has been amended to depend from new Claim 133.

49. **Pending – Amended.** Claim 49 has been amended to depend from new Claim 133.

50. **Pending – Unchanged.**

51. **Pending – Unchanged.**

52. **Pending – Amended.** Claim 52 has been amended to depend from new Claim 133.

53. **Canceled.**

54. **Pending – Unchanged.**

55. **Pending – Unchanged.**

56. **Pending – Unchanged.**

57. **Pending – Amended.** Claim 57 has been amended to depend from new Claim 134.

58. **Pending – Unchanged.**

59. **Pending – Unchanged.**

60. **Pending – Unchanged.**

61. **Pending – Amended.** Claim 61 has been amended to depend from new Claim 134.

62. **Pending – Unchanged.**

63. **Pending – Unchanged.**

64. **Pending – Unchanged.**

65. **Pending – Unchanged.**

66. **Pending – Unchanged.**

67. **Pending – Amended.** Claim 67 has been amended to depend from new Claim 134.

68. **Pending – Unchanged.**

69. **Pending – Unchanged.**

70. **Pending – Unchanged.**

71. **Pending – Unchanged.**

72. **Pending – Amended.** Claim 72 has been amended to depend from new Claim 134.

73. **Pending – Amended.** Claim 73 has been amended to depend from new Claim 134.

74. **Pending – Amended.** Claim 74 has been amended to depend from new Claim 134.

75. **Pending – Unchanged.**

76. **Pending – Unchanged.**

77. **Pending – Amended.** Claim 74 has been amended to depend from new Claim 134.

78. **Pending – Amended.** Claim 78 has been amended to depend from new Claim 134.

79. **Pending – Amended.** Claim 79 has been amended to depend from new Claim 134.

80. **Canceled.**

81. **Pending – Unchanged.**

82. **Pending – Unchanged.**

83. **Pending – Unchanged.**

84. **Pending – Amended.** Claim 84 has been amended to depend from new Claim 135.

85. **Pending – Unchanged.**

86. **Pending – Unchanged.**

87. **Pending – Unchanged.**

88. **Pending – Amended.** Claim 88 has been amended to depend from new Claim 135.

89. **Pending – Unchanged.**

90. **Pending – Unchanged.**

91. **Pending – Unchanged.**

92. **Pending – Unchanged.**

93. **Pending – Unchanged.**

94. **Pending – Amended.** Claim 94 has been amended to depend from new Claim 135.

95. **Pending – Unchanged.**

96. **Pending – Unchanged.**

97. **Pending – Unchanged.**

98. **Pending – Unchanged.**

99. **Pending – Amended.** Claim 99 has been amended to depend from new Claim 135.

100. **Pending – Amended.** Claim 100 has been amended to depend from new Claim 135.

101. **Pending – Amended.** Claim 101 has been amended to depend from new Claim 135.

102. **Pending – Unchanged.**

103. **Pending – Unchanged.**

104. **Pending – Amended.** Claim 104 has been amended to depend from new Claim 135.

105. **Pending – Amended.** Claim 105 has been amended to depend from new Claim 135.

106. **Pending – Amended.** Claim 106 has been amended to depend from new Claim 135.

107. **Canceled.**

108. **Pending – Unchanged.**

109. **Pending – Unchanged.**

110. **Pending – Unchanged.**

111. **Pending – Amended.** Claim 111 has been amended to depend from new Claim 136.

112. **Pending – Unchanged.**

113. **Pending – Unchanged.**

114. **Pending – Unchanged.**

115. **Pending – Unchanged.**

116. **Pending – Unchanged.**

117. **Pending – Unchanged.**

118. **Pending – Unchanged.**

119. **Pending – Unchanged.**

120. **Pending – Amended.** Claim 120 has been amended to depend from new Claim 136.

121. **Pending – Unchanged.**

122. **Pending – Unchanged.**

123. **Pending – Unchanged.**

124. **Pending – Unchanged.**

125. **Pending – Amended.** Claim 125 has been amended to depend from new Claim 136.

126. **Pending – Amended.** Claim 126 has been amended to depend from new Claim 136.

127. **Pending – Amended.** Claim 127 has been amended to depend from new Claim 136.

128. **Pending – Unchanged.**

129. **Pending – Unchanged.**

130. **Pending – Amended.** Claim 130 has been amended to depend from new Claim 136.

131. **Pending – Amended.** Claim 131 has been amended to depend from new Claim 136.

132. **Pending – Amended.** Claim 132 has been amended to depend from new Claim 136.

133. **Pending – New.** New Claim 133 includes all limitations of previous Claim 28 and also includes the limitation that "at least 95% of glucose concentration values measured by the signal are within 25% of corresponding reference values obtained periodically throughout the continuous glucose sensing, and wherein the plurality of reference values are determined by analysis of blood." Support for this limitation can be found, *e.g.*, at Col. 2, Lns. 30-34 and Col. 4, Lns. 30-36 of the '562 Patent.

134. **Pending – New.** New Claim 134 includes all limitations of previous Claim 53 and also includes the limitation that "the device is configured to prevent motion artifact." Support for this limitation can be found, *e.g.*, at Col. 2, Lns. 27-30 of the '562 Patent.

135. **Pending – New.** New Claim 135 includes all limitations of previous Claim 80 and also includes the limitation that "the membrane comprises a cross-linked polymer." Support for

this limitation can be found, *e.g.*, at Col. 15, Lns. 15-37 and Col. 18, Lns. 40-45 of the '562 Patent.

136. **Pending – New.** New Claim 136 includes all limitations of previous Claim 107 and also includes the limitation that "the membrane is further configured to block interfering species." Support for this limitation can be found, *e.g.*, at Col. 14, Lns. 9-24 of the '562 Patent.

REMARKS

Claim Status

Claims 1, 5, 9, 15, 20-22, 25-28, 32, 36, 42, 47-49, 52, 53, 57, 61, 67, 72-74, 77-80, 84, 88, 94, 99-101, 104-107, 111, 120, 125-127, and 130-132 of the '562 Patent are currently under reexamination. By virtue of this Amendment, Claims 32, 36, 42, 47-49, 52, 57, 61, 67, 72-74, 77-79, 84, 88, 94, 99-101, 104-106, 111, 120, 125-127, and 130-132 have been amended, Claims 28, 53, 80, and 107 have been canceled, and new Claims 133-136 have been added. Accordingly, upon entry of the Amendment, Claims 1, 5, 9, 15, 20-22, 25-27, 32, 36, 42, 47-49, 52, 57, 61, 67, 72-74, 77-79, 84, 88, 94, 99-101, 104-106, 111, 120, 125-127, and 130-136 will be under reexamination.

Prior Art Rejections

A. Claims 1, 5, 9, 15, 20, 26-28, 32, 36, 42, 47, 53, 57, 61, 72, 78-80, 84, 88, 99, 105-107, 111, 125, 131, and 132 are patentable over U.S. Patent No. 5,322,063 ("Allen").

Claims 1, 5, 9, 15, 20, 26-28, 32, 36, 42, 47, 53, 57, 61, 72, 78-80, 84, 88, 99, 105-107, 111, 125, 131, and 132 stand rejected under 35 U.S.C. 102(b) as allegedly anticipated by Allen. The Patent Owner respectfully traverses this anticipatory rejection. "A rejection for anticipation under section 102 requires that each and every limitation of the claimed invention be disclosed in a single prior art reference." *See, e.g., In re Paulsen*, 31 U.S.P.Q.2d 1671 (Fed. Cir. 1994).

Claim 1, from which Claims 5, 9, 15, 20, and 26-27 depend, recites:

> 1. A device for measuring a glucose concentration in a host, the device comprising: a sensor operably connected to an electronic circuit and configured to continuously measure a signal indicative of a glucose concentration in a host for a period of time; and a membrane located over at least a portion of the sensor, wherein the membrane is configured to control a flux of oxygen and glucose; wherein the device is capable of exhibiting, at a glucose concentration of about 400 mg/dL, no more than a 10% drop in sensor output over a range of pO_2 from about 150 mm Hg down to about 30 mm Hg, and wherein **the device is configured to use an *in vitro* calibration factor for initial calibration**. [Bolding added for emphasis.]

The Patent Owner respectfully submits that Allen fails to disclose a device configured to use an *in vitro* calibration factor for initial calibration. Indeed, in the Office Action mailed April 18, 2011, the Examiner fails to describe how Allen discloses a device configured to use an *in vitro* calibration factor for initial calibration. Rather, the Examiner merely suggests that "Allen teaches *in vitro* testing of the device," which is a teaching that is wholly different from the recited

limitation of a device configured to use an *in vitro* calibration factor for initial calibration. For at least the reason that Allen does not teach all elements of Claim 1, the Patent Owner submits that the anticipatory rejection of Claims 1, 5, 9, 15, 20, 26, and 27 is improper and thus respectfully request that it be withdrawn.

Claim 28, from which Claims 32, 36, 42, and 47 previously depended, has been canceled and replaced with Claim 133. Claims 32, 36, 42, and 47 have been amended to now depend from Claim 133. Claim 133 includes all limitations of previous Claim 28 and includes the limitation "whereby at least 95% of glucose concentration values measured by the signal are within 25% of corresponding reference values obtained periodically throughout the continuous glucose sensing, and wherein the plurality of reference values are determined by analysis of blood." Support for this limitation can be found, *e.g.*, at Col. 2, Lns. 30-34 and Col. 4, Lns. 30-36 of the '562 Patent. The Patent Owner respectfully submits that Allen fails to disclose a device capable of exhibiting this level of accuracy. For at least the reason that Allen does not teach all elements of Claim 133, the Patent Owner submits that new Claim 133 is distinguished from Allen and that the anticipatory rejection of Claims 32, 36, 42, and 47 cannot stand. Accordingly, withdrawal of this anticipatory rejection is respectfully requested.

Claim 53, from which Claims 57, 61, 72, 78, and 79 previously depended, has been canceled and replaced with Claim 134. Claims 57, 61, 72, 78, and 79 have been amended to now depend from Claim 134. Claim 134 includes all limitations of previous Claim 53 and includes the limitation that "the device is configured to prevent motion artifact." Support for this limitation can be found, *e.g.*, at Col. 2, Lns. 27-30 of the '562 Patent. The Patent Owner respectfully submits that Allen fails to disclose a device configured to prevent motion artifact. For at least the reason that Allen does not teach all elements of Claim 134, the Patent Owner submits that new Claim 134 is distinguished from Allen and that the anticipatory rejection of Claims 57, 61, 72, 78, and 79 cannot stand. Accordingly, withdrawal of this anticipatory rejection is respectfully requested.

Claim 80, from which Claims 84, 88, 99, 105, and 106 previously depended, has been canceled and replaced with Claim 135. Claims 84, 88, 99, 105, and 106 have been amended to now depend from Claim 135. Claim 135 includes all limitations of previous Claim 80 and includes the limitation that the device's "membrane comprises a cross-linked polymer." Support for this

limitation can be found, *e.g.*, at Col. 15, Lns. 15-37 and Col. 18, Lns. 40-45 of the '562 Patent. The Patent Owner respectfully submits that Allen fails to disclose a device with a membrane comprising a cross-linked polymer. In fact, Allen appears to teach away from using a cross-linked polymer when it states in Col. 3, Ln. 65 – Col. 4, Ln. 1 that "[s]ince these polymers do not have to be crosslinked in order to develop optimum properties, they are soluble in a variety of solvents and solvent combinations, and thus can be readily fabricated into membranes of various shapes." For at least the reason that Allen does not teach all elements of Claim 135, the Patent Owner submits that new Claim 135 is distinguished from Allen and that the anticipatory rejection of Claims 84, 88, 99, 105, and 106 cannot stand. Accordingly, withdrawal of this anticipatory rejection is respectfully requested.

Claim 107, from which Claims 111, 125, 131, and 132 previously depended, has been canceled and replaced with Claim 136. Claims 111, 125, 131, and 132 have been amended to now depend from Claim 136. Claim 136 includes all limitations of previous Claim 107 and includes the limitation that the device's "membrane is further configured to block interfering species." Support for this limitation can be found, *e.g.*, at Col. 14, Lns. 9-24 of the '562 Patent. The Patent Owner respectfully submits that Allen fails to disclose a device with a membrane configured to block interfering species. For at least the reason that Allen does not teach all elements of Claim 136, the Patent Owner submits that new Claim 136 is distinguished from Allen and that the anticipatory rejection of Claims 111, 125, 131, and 132 cannot stand. Accordingly, withdrawal of this anticipatory rejection is respectfully requested.

B. Claims 28, 32, 36, 53, 57, 61, 78-80, 84, 88, 105-107, 111, 131, and 132 are patentable over Kusano, H., Glucose enzyme electrode with percutaneous interface which operates independently of dissolved oxygen, *Clin. Phys. Physiol. Meas.*, vol. 10, 1:1-9 (1989) ("Kusano")

Claims 28, 32, 36, 53, 57, 61, 78-80, 84, 88, 105-107, 111, 131, and 132 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by Kusano. The criteria for anticipation are set forth above. The Patent Owner respectfully traverses this anticipatory rejection.

First, the Patent Owner respectfully submits that Kusano does not disclose a device "capable of exhibiting, at a glucose concentration of about 400 mg/dL, no more than 10% drop in sensor output over a range of pO_2 from about 150 mm Hg down to about 30 mm Hg." More specifically, as illustrated in Figure 2, Kusano's device employs an air intake through which

ambient oxygen from the air is supplied to the electrode. *See*, *e.g.*, Pg. 3 of Kusano. Because of the continuous supply of ambient oxygen through the air intake, Kusano's sensor is not designed to (and is not) "capable of exhibiting, at a glucose concentration of about 400 mg/dL, no more than 10% drop in sensor output over a range of pO_2 from about 150 mm Hg down to about 30 mm Hg.". Rather, based on Kusano's description, it would appear to those skilled in the art that the Kusano sensor is designed to operate at (or near) an oxygen partial pressure corresponding to that of ambient air, i.e., at a pO_2 of about 159 mm Hg.[1] *See also* Pg. 7 of Kusano, which states that "the upper part of [the Kusano device's] electrode is exposed in air. This feature was exploited to the best advantage, that is by utilizing oxygen in the air for the oxidation of the glucose." For at least the reason that Kusano does not teach a device that is "capable of exhibiting, at a glucose concentration of about 400 mg/dL, no more than 10% drop in sensor output over a range of pO_2 from about 150 mm Hg down to about 30 mm Hg," the Patent Owner submits that the anticipatory rejection of Claims 28, 32, 36, 53, 57, 61, 78-80, 84, 88, 105-107, 111, 131, and 132 is improper and thus respectfully request that it be withdrawn.

C. Claims 15, 21, 22, 42, 48, 49, 67, 73, 74, 94, 100, 101, 120, 126, and 127 are patentable over Allen in view of Moatti-Sirat et al., Towards continuous glucose monitoring: in vivo evaluation of a miniaturized glucose sensor implanted for several days in rat subcutaneous tissue, Diabetologia, 35:244-230 (1992) ("Moatti-Sirat")

Claims 15, 21, 22, 42, 48, 49, 67, 73, 74, 94, 100, 101, 120, 126, and 127 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Allen in view of Moatti-Sirat. The Patent Owner respectfully traverses this obviousness rejection.

It is well settled that the Examiner "bears the initial burden of presenting a *prima facie* case of unpatentability…" *In re Sullivan*, 498 F.3d 1345 (Fed. Cir. 2007). Until the Examiner has established a *prima facie* case of obviousness, Applicants need not present arguments or evidence of non-obviousness. To establish a *prima facie* case of obviousness, the Examiner must establish at least three elements. First, the prior art reference (or references when combined) must teach or suggest all of the claim limitations: "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 165 U.S.P.Q.

[1] See, e.g., atmospheric pO_2 at 0 meters altitude, Table 1, page 449 of Samuels, M.P. "The effects of flight and altitude" *Arch Dis Child* 2004;**89**:448–455, included in the Information Disclosure

494, 496 (CCPA 1970); *see also M.P.E.P. § 2143.03*. Second, there must be a reasonable expectation of success. *In re Merck & Co., Inc.*, 800 F.2d 1091 (Fed. Cir. 1986); *see also M.P.E.P. § 2143.02*. And finally, the Examiner must articulate some reason to modify or combine the cited references that renders the claim obvious. Merely establishing that the claimed elements can be found in the prior art is not sufficient to establish a *prima facie* case of obviousness:

> As is clear from cases such as *Adams,* a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) (emphasis added).

Instead, the Court has made clear that the Examiner must establish a reason one of skill in the art would have combined the elements of the prior art, and that such reason must be more than a conclusory statement that it would have been obvious.

Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicit. *See In re Kahn,* 441 F.3d 977, 988 (C.A.Fed.2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness"). *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1740-1741 (2007) (emphasis added).

Claims 15, 42, 67, 94, and 120 each recite an accuracy level corresponding to having "at least 95% of glucose concentration values measured by the signal [being] within 25% of an actual value over the period of time, and wherein the actual value is determined by analysis of blood."

According to the Examiner:

> Allen is silent as to at least 95% of glucose concentration values measured are within 25% of corresponding values determined by analysis of blood over the period of time… Moatti-Sirat teaches experimental results that show that 99% of the time, values fall within a Zone A, which deviates no more than 20% from the reference… Accordingly, it would have been obvious to one ordinary skill in the

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Statement filed herewith.

> art at the time the invention was made to modify the sensor of Allen to include the sensor/membrane combination taught by Moatti-Sirat, to arrive at the level of accuracy obtained by Moatti-Sirat.

Office Action mailed April 18, 2011, at page 7.

The Patent Owner respectfully disagrees. Contrary to the Examiner's contention, the Patent Owner submits that modifying and/or replacing the membrane of Allen's device with the membrane disclosed in Moatti-Sirat would not have resulted in the claimed invention and/or would not have yielded predictable results. Allen teaches a glucose sensor with a membrane that is specifically designed to "[render] the sensor insensitive to changes in the oxygen levels of subcutaneous fluids." *See* Col. 4, Lns 10-12. Indeed, the Allen membrane is "prepared from biologically acceptable polymers whose hydrophobic/hydrophilic balance can be varied over a wide range to control the ratio of the diffusion coefficient of oxygen to that of glucose…" *See* Col. 3, Lns. 44-48. In contrast, Moatti-Sirat merely teaches using a polyurethane layer, with an unspecified composition, to form a membrane around the glucose sensor. *See* page 224 of Moatti-Sirat. To replace or modify Allen's membrane, which incorporates a particular hydrophobic/hydrophilic balance to achieve insensitivity to changes in oxygen levels in subcutaneous fluids, with Moatti-Sirat's polyurethane layer, would not have seemingly resulted in the claimed invention and/or not yielded predictable results, namely, "capable of exhibiting, at a glucose concentration of about 400 mg/dL, no more than 10% drop in sensor output over a range of pO_2 from about 150 mm Hg down to about 30 mm Hg." Indeed, to modify or replace the membrane of Allen with the membrane of Moatti-Sirat cannot be considered a simple substitution of one element for another to obtain predictable results. Furthermore, because of the many differences that exist between Allen's sensor configuration and Moatti-Sirat's sensor configuration, it cannot be presumed that the proposed modification would have resulted in a sensor that achieves an accuracy level corresponding to having at least 95% of glucose concentration values measured by the signal being within 25% of an actual value over the period of time, and wherein the actual value is determined by analysis of blood. For at least this reason, the Patent Owner submits that this obviousness rejection is improper and thus should be withdrawn.

Claims 20-22, 47-49, 72-74, 99-101, and 125-127 each recite a particular period of time — 3, 5, or 7 days — that the sensor is configured to continuously measure a signal indicative of a glucose concentration in a host. As noted above, the Patent Owner submits that replacing or modifying Allen's membrane with Moatti-Sirat's membrane would seemingly result in a device incapable of performing at the low oxygen levels described in Allen and recited in the pending claims. For at least this reason, the Patent Owner submits that this obviousness rejection is improper and thus should be withdrawn.

In addition, with specific regard to Claims 15, 21, and 22, each of these claims depend on Claim 1, which recites a device configured to use an *in vitro* calibration factor for initial calibration. As noted above, Allen fails to teach a device configured to use an *in vitro* calibration factor for initial calibration. Moatti-Sirat also fails to teach a device with such a feature. In fact, page 229 of Moatti-Sirat teaches that "there was no correlation between the in vivo sensitivity and the corresponding in vitro sensitivity of the same sensor (data not shown). This suggests that the in vivo sensitivity is mainly dependent on the in situ environment of the sensor, confirming the need for in vivo calibration." Accordingly, for at least the reason that neither Allen nor Moatti-Sirat teaches a device configured to use an *in vitro* calibration factor for initial calibration, the Patent Owner submits that the combined teachings of Allen and Moatti-Sirat would not have arrived at the claimed invention. Accordingly, the Patent Owner submits that this obviousness rejection of Claims 15, 21, and 22 cannot stand and thus should be withdrawn.

D. Claims 25, 52, 77, 104, and 130 are patentable over Allen in view of Csöregi et al., Design, Characterization and One-Point in Vivo Calibration of a Subcutaneously Implanted Glucose Electrode, Analytical Chemistry, 66(19):3131-3138 (October 1, 1994) ("Csöregi").

Claims 25, 52, 77, 104, and 130 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Allen in view of Csöregi. The Patent Owner respectfully traverses this obviousness rejection. The criteria for establishing a *prima facie* case of obviousness are set forth above.

Claim 25 depends on Claim 1, which recites that "the device is configured to use an *in vitro* calibration factor for initial calibration." As noted above, Allen does not teach this feature. Csöregi also does not teach this feature. Accordingly, for at least the reason that neither Allen nor Csöregi teaches a device is configured to use an *in vitro* calibration factor for initial

calibration, the Patent Owner submits that the combined teachings of Allen and Csöregi would not have arrived at the claimed invention. Accordingly, the Patent Owner submits that this obviousness rejection cannot stand and thus should be withdrawn.

Claim 52 depends on Claim 133, which recites "at least 95% of glucose concentration values measured by the signal [being] within 25% of corresponding reference values obtained periodically throughout the continuous glucose sensing, and wherein the plurality of reference values are determined by analysis of blood." As noted above, Allen does not teach a device that achieves this level of accuracy. Csöregi also does not teach such a device. Accordingly, for at least the reason that neither Allen nor Csöregi teaches a device that achieves the above-described level of accuracy, the Patent Owner submits that the combined teachings of Allen and Csöregi would not have arrived at the claimed invention. Accordingly, the Patent Owner submits that this obviousness rejection cannot stand and thus should be withdrawn.

Claim 77 depends on Claim 134, which recites that "the device is configured to prevent motion artifact." As noted above, Allen does not teach this feature. Csöregi also does not teach this feature. Accordingly, for at least the reason that neither Allen nor Csöregi teaches a device configured to prevent motion artifact, the Patent Owner submits that the combined teachings of Allen and Csöregi would not have arrived at the claimed invention. Accordingly, the Patent Owner submits that this obviousness rejection cannot stand and thus should be withdrawn.

Claim 104 depends on Claim 135, which recites that the device's "membrane comprises a cross-linked polymer." As noted above, Allen does not teach this feature. While Csöregi may teach an outer biocompatible layer that comprises a cross-linked polymer, the Patent Owner submits that replacing or modifying Allen's membrane with Csöregi's membrane would seemingly result in a device incapable of performing at the low oxygen levels described in Allen and recited in the pending claims. For at least this reason, the Patent Owner submits that this obviousness rejection is improper and thus should be withdrawn.

Claim 130 depends on Claim 136, which recites that "membrane is further configured to block interfering species." As noted above, Allen does not teach this feature. Csöregi also does not teach this feature. Accordingly, for at least the reason that neither Allen nor Csöregi teaches a membrane configured to block interfering species, the Patent Owner submits that the combined

teachings of Allen and Csöregi would not have arrived at the claimed invention. Accordingly, the Patent Owner submits that this obviousness rejection cannot stand and thus should be withdrawn.

E. Claims 1, 5, 9, 26, and 27 are patentable over Kusano in view of Mastrototaro.

Claims 1, 5, 9, 26, and 27 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Kusano in view of Mastrototaro. The Patent Owner respectfully traverses this obviousness rejection. The criteria for establishing a *prima facie* case of obviousness are set forth above.

Claim 1, from which Claims 5, 9, 26, and 27 depend, recite a device "capable of exhibiting, at a glucose concentration of about 400 mg/dL, no more than 10% drop in sensor output over a range of pO_2 from about 150 mm Hg down to about 30 mm Hg." As noted above, Kusano does not teach this capability, because Kusano's sensor is designed to operate in an environment that receives a continuous supply of ambient oxygen through the air intake. Mastrototaro also does not teach a device "capable of exhibiting, at a glucose concentration of about 400 mg/dL, no more than 10% drop in sensor output over a range of pO_2 from about 150 mm Hg down to about 30 mm Hg." Accordingly, for at least the reason that neither Kusano nor Mastrototaro teaches a device "capable of exhibiting, at a glucose concentration of about 400 mg/dL, no more than 10% drop in sensor output over a range of pO_2 from about 150 mm Hg down to about 30 mm Hg," the Patent Owner submits that the combined teachings of Kusano and Mastrototaro would not have arrived at the claimed invention. Accordingly, the Patent Owner submits that this obviousness rejection cannot stand and thus should be withdrawn.

F. Claims 15 and 20-22 are patentable over Kusano in view of Mastrototaro and further in view of Moatti-Sirat.

Claims 15 and 20-22 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Kusano in view of Mastrototaro and further in view of Moatti-Sirat. The Patent Owner respectfully traverses this obviousness rejection. The criteria for establishing a *prima facie* case of obviousness are set forth above.

Claims 15 and 20-22 depend from Claim 1, which recites a device "capable of exhibiting, at a glucose concentration of about 400 mg/dL, no more than 10% drop in sensor output over a range of pO_2 from about 150 mm Hg down to about 30 mm Hg." As noted above, neither Kusano nor Mastrototaro teaches this capability. Moatti-Sirat also does not teach a device

"capable of exhibiting, at a glucose concentration of about 400 mg/dL, no more than 10% drop in sensor output over a range of pO_2 from about 150 mm Hg down to about 30 mm Hg." Accordingly, for at least the reason that none of Kusano, Mastrototaro, or Moatti-Sirat teaches a device "capable of exhibiting, at a glucose concentration of about 400 mg/dL, no more than 10% drop in sensor output over a range of pO_2 from about 150 mm Hg down to about 30 mm Hg," the Patent Owner submits that the combined teachings of Kusano, Mastrototaro, and Moatti-Sirat would not have arrived at the claimed invention. Accordingly, the Patent Owner submits that this obviousness rejection cannot stand and thus should be withdrawn.

G. Claim 25 is patentable over Kusano in view of Mastrototaro and in further view of Csöregi.

Claim 25 stands rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Kusano in view of Mastrototaro and further in view of Csöregi. The Patent Owner respectfully traverses this obviousness rejection. The criteria for establishing a *prima facie* case of obviousness are set forth above.

Claim 25 depends from Claim 1, which recites a device "capable of exhibiting, at a glucose concentration of about 400 mg/dL, no more than 10% drop in sensor output over a range of pO_2 from about 150 mm Hg down to about 30 mm Hg." As noted above, neither Kusano nor Mastrototaro teaches this capability. Csöregi also does not teach a device "capable of exhibiting, at a glucose concentration of about 400 mg/dL, no more than 10% drop in sensor output over a range of pO_2 from about 150 mm Hg down to about 30 mm Hg." Accordingly, for at least the reason that none of Kusano, Mastrototaro, or Csöregi teaches a device "capable of exhibiting, at a glucose concentration of about 400 mg/dL, no more than 10% drop in sensor output over a range of pO_2 from about 150 mm Hg down to about 30 mm Hg," the Patent Owner submits that the combined teachings of Kusano, Mastrototaro, and Csöregi would not have arrived at the claimed invention. Accordingly, the Patent Owner submits that this obviousness rejection cannot stand and thus should be withdrawn.

H. Claims 42, 47-49, 67, 72-74, 94, 99-101, 120, and 125-127 are patentable over Kusano in view of Moatti-Sirat.

Claims 42, 47-49, 67, 72-74, 94, 99-101, 120, and 125-127 have been amended to depend from either Claims 133, 134, 135, or 136, each of which recites a device "capable of exhibiting, at

a glucose concentration of about 400 mg/dL, no more than 10% drop in sensor output over a range of pO_2 from about 150 mm Hg down to about 30 mm Hg." As noted above, neither Kusano nor Moatti-Sirat teaches this capability. Thus, the Patent Owner submits that the combined teachings of Kusano and Moatti-Sirat would not have arrived at the claimed invention. Accordingly, the Patent Owner submits that this obviousness rejection cannot stand and thus should be withdrawn.

I. Claims 52, 77, 104, and 130 are patentable over Kusano in view of Csöregi.

Claims 52, 77, 104, and 130 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Kusano in view of Csöregi. The Patent Owner respectfully traverses this obviousness rejection. The criteria for establishing a *prima facie* case of obviousness are set forth above.

Claims 52, 77, 104, and 130 have been amended to depend from Claims 133, 134, 135, and 136, respectively, each of which recites a device "capable of exhibiting, at a glucose concentration of about 400 mg/dL, no more than 10% drop in sensor output over a range of pO_2 from about 150 mm Hg down to about 30 mm Hg." As noted above, neither Kusano nor Csöregi teaches this feature. Thus, the Patent Owner submits that the combined teachings of Kusano and Csöregi would not have arrived at the claimed invention. Accordingly, the Patent Owner submits that this obviousness rejection cannot stand and thus should be withdrawn.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Patent Owner is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Patent Owner reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child, or related prosecution history shall not reasonably infer that Patent Owner has made any disclaimers or disavowals of any subject matter supported by the present application.

Co-Pending Applications of Assignee

Patent Owner wishes to draw the Examiner's attention to the following applications of the present application's assignee.

Docket No.	Serial No.	Title	Filed
DEXCOM.9CPDVC	07/122395	BIOLOGICAL FLUID MEASURING DEVICE	11/19/1987
DEXCOM.9CPDCP	07/216683	BIOLOGICAL FLUID MEASURING DEVICE	7/7/1988
DEXCOM.008A	08/811473	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	3/4/1997
DEXCOM.008DV1	09/447227	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	11/22/1999
DEXCOM.8DVC1	09/489588	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	1/21/2000
DEXCOM.8DVCP1	09/636369	SYSTEMS AND METHODS FOR REMOTE MONITORING AND MODULATION OF MEDICAL DEVICES	8/11/2000
DEXCOM.006A	09/916386	MEMBRANE FOR USE WITH IMPLANTABLE DEVICES	7/27/2001
DEXCOM.007A	09/916711	SENSOR HEAD FOR USE WITH IMPLANTABLE DEVICE	7/27/2001
DEXCOM.8DVCP2	09/916858	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	7/27/2001
DEXCOM.010A	10/153356	TECHNIQUES TO IMPROVE POLYURETHANE MEMBRANES FOR IMPLANTABLE GLUCOSE SENSORS	5/22/2002
DEXCOM.024A	10/632537	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	8/1/2003
DEXCOM.026A	10/633329	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	8/1/2003
DEXCOM.016A	10/633367	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	8/1/2003
DEXCOM.025A	10/633404	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	8/1/2003
DEXCOM.011A	10/646333	OPTIMIZED SENSOR GEOMETRY FOR AN IMPLANTABLE GLUCOSE SENSOR	8/22/2003
DEXCOM.012A	10/647065	POROUS MEMBRANES FOR USE WITH IMPLANTABLE DEVICES	8/22/2003

DEXCOM.027A	10/648849	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	8/22/2003
DEXCOM.8DVC1C1	10/657843	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	9/9/2003
DEXCOM.028A	10/695636	SILICONE COMPOSITION FOR BIOCOMPATIBLE MEMBRANE	10/28/2003
DEXCOM.006C1	10/768889	MEMBRANE FOR USE WITH IMPLANTABLE DEVICES	1/29/2004
DEXCOM.037A	10/789359	INTEGRATED DELIVERY DEVICE FOR CONTINUOUS GLUCOSE SENSOR	2/26/2004
DEXCOM.045A	10/838658	IMPLANTABLE ANALYTE SENSOR	5/3/2004
DEXCOM.044A	10/838909	IMPLANTABLE ANALYTE SENSOR	5/3/2004
DEXCOM.043A	10/838912	IMPLANTABLE ANALYTE SENSOR	5/3/2004
DEXCOM.012CP1	10/842716	BIOINTERFACE MEMBRANES INCORPORATING BIOACTIVE AGENTS	5/10/2004
DEXCOM.8DV1CP	10/846150	ANALYTE MEASURING DEVICE	5/14/2004
DEXCOM.048A	10/885476	SYSTEMS AND METHODS FOR MANUFACTURE OF AN ANALYTE-MEASURING DEVICE INCLUDING A MEMBRANE SYSTEM	7/6/2004
DEXCOM.019A	10/896637	ROLLED ELECTRODE ARRAY AND ITS METHOD FOR MANUFACTURE	7/21/2004
DEXCOM.021A	10/896639	OXYGEN ENHANCING MEMBRANE SYSTEMS FOR IMPLANTABLE DEVICES	7/21/2004
DEXCOM.020A	10/896772	INCREASING BIAS FOR OXYGEN PRODUCTION IN AN ELECTRODE SYSTEM	7/21/2004
DEXCOM.023A	10/897312	ELECTRODE SYSTEMS FOR ELECTROCHEMICAL SENSORS	7/21/2004
DEXCOM.022A	10/897377	ELECTROCHEMICAL SENSORS INCLUDING ELECTRODE SYSTEMS WITH INCREASED OXYGEN GENERATION	7/21/2004
DEXCOM.030A	10/991353	AFFINITY DOMAIN FOR ANALYTE SENSOR	11/16/2004
DEXCOM.032A	10/991966	INTEGRATED RECEIVER FOR CONTINUOUS ANALYTE SENSOR	11/17/2004
DEXCOM.038A	11/004561	CALIBRATION TECHNIQUES FOR A CONTINUOUS ANALYTE SENSOR	12/3/2004

DEXCOM.031A	11/007635	SYSTEMS AND METHODS FOR IMPROVING ELECTROCHEMICAL ANALYTE SENSORS	12/7/2004
DEXCOM.029A	11/007920	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	12/8/2004
DEXCOM.008DV1C	11/021046	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	12/22/2004
DEXCOM.007C1	11/021162	SENSOR HEAD FOR USE WITH IMPLANTABLE DEVICES	12/22/2004
DEXCOM.040A	11/034343	COMPOSITE MATERIAL FOR IMPLANTABLE DEVICE	1/11/2005
DEXCOM.039A	11/034344	IMPLANTABLE DEVICE WITH IMPROVED RADIO FREQUENCY CAPABILITIES	1/11/2005
DEXCOM.024C1	11/038340	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	1/18/2005
DEXCOM.8DVCP2C	11/039269	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	1/19/2005
DEXCOM.034A	11/055779	BIOINTERFACE MEMBRANE WITH MACRO- AND MICRO-ARCHITECTURE	2/9/2005
DEXCOM.051A8	11/077643	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
DEXCOM.051A5	11/077693	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
DEXCOM.051A4	11/077713	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
DEXCOM.051A6	11/077714	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
DEXCOM.051A	11/077715	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
DEXCOM.051A10	11/077739	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
DEXCOM.051A11	11/077740	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
DEXCOM.050A	11/077759	TRANSCUTANEOUS MEDICAL DEVICE WITH VARIABLE STIFFNESS	3/10/2005
DEXCOM.051A7	11/077763	METHOD AND SYSTEMS FOR INSERTING A TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
DEXCOM.051A12	11/077765	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
DEXCOM.051A1	11/077883	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005

DEXCOM.051A9	11/078072	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
DEXCOM.051A2	11/078230	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
DEXCOM.051A3	11/078232	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
DEXCOM.061A1	11/157365	TRANSCUTANEOUS ANALYTE SENSOR	6/21/2005
DEXCOM.061A	11/157746	TRANSCUTANEOUS ANALYTE SENSOR	6/21/2005
DEXCOM.061A2	11/158227	TRANSCUTANEOUS ANALYTE SENSOR	6/21/2005
DEXCOM.016C1	11/201445	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	8/10/2005
DEXCOM.010DV2	11/280102	TECHNIQUES TO IMPROVE POLYURETHANE MEMBRANES FOR IMPLANTABLE GLUCOSE SENSORS	11/16/2005
DEXCOM.010DV1	11/280672	TECHNIQUES TO IMPROVE POLYURETHANE MEMBRANES FOR IMPLANTABLE GLUCOSE SENSORS	11/16/2005
DEXCOM.063A	11/333837	LOW OXYGEN IN VIVO ANALYTE SENSOR	1/17/2006
DEXCOM.061CP1	11/334107	TRANSCUTANEOUS ANALYTE SENSOR	1/17/2006
DEXCOM.061CP2	11/334876	TRANSCUTANEOUS ANALYTE SENSOR	1/18/2006
DEXCOM.058A	11/335879	CELLULOSIC-BASED INTERFERENCE DOMAIN FOR AN ANALYTE SENSOR	1/18/2006
DEXCOM.077A	11/360250	ANALYTE SENSOR	2/22/2006
DEXCOM.061CP3	11/360252	ANALYTE SENSOR	2/22/2006
DEXCOM.051CP1	11/360262	ANALYTE SENSOR	2/22/2006
DEXCOM.051CP2	11/360299	ANALYTE SENSOR	2/22/2006
DEXCOM.061CP4	11/360819	ANALYTE SENSOR	2/22/2006
DEXCOM.053A	11/373628	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA FOR SENSOR CALIBRATION	3/9/2006
DEXCOM.075A	11/404417	SILICONE BASED MEMBRANES FOR USE IN IMPLANTABLE GLUCOSE SENSORS	4/14/2006
DEXCOM.010CP1	11/404418	SILICONE BASED MEMBRANES FOR USE IN IMPLANTABLE GLUCOSE SENSORS	4/14/2006

DEXCOM.054A1	11/404421	ANALYTE SENSING BIOINTERFACE	4/14/2006
DEXCOM.054A	11/404929	ANALYTE SENSING BIOINTERFACE	4/14/2006
DEXCOM.054A2	11/404946	ANALYTE SENSING BIOINTERFACE	4/14/2006
DEXCOM.021C1	11/410392	OXYGEN ENHANCING MEMBRANE SYSTEMS FOR IMPLANTABLE DEVICES	4/25/2006
DEXCOM.021DV1	11/410555	OXYGEN ENHANCING MEMBRANE SYSTEMS FOR IMPLANTABLE DEVICES	4/25/2006
DEXCOM.051CP1C1	11/411656	ANALYTE SENSOR	4/26/2006
DEXCOM.060A	11/413238	CELLULOSIC-BASED RESISTANCE DOMAIN FOR AN ANALYTE SENSOR	4/28/2006
DEXCOM.060A2	11/413242	CELLULOSIC-BASED RESISTANCE DOMAIN FOR AN ANALYTE SENSOR	4/28/2006
DEXCOM.060A1	11/413356	CELLULOSIC-BASED RESISTANCE DOMAIN FOR AN ANALYTE SENSOR	4/28/2006
DEXCOM.051C1	11/415593	TRANSCUTANEOUS ANALYTE SENSOR	5/2/2006
DEXCOM.011DV3	11/415631	OPTIMIZED SENSOR GEOMETRY FOR AN IMPLANTABLE GLUCOSE SENSOR	5/2/2006
DEXCOM.051C3	11/415999	TRANSCUTANEOUS ANALYTE SENSOR	5/2/2006
DEXCOM.011DV1	11/416058	OPTIMIZED SENSOR GEOMETRY FOR AN IMPLANTABLE GLUCOSE SENSOR	5/2/2006
DEXCOM.011DV2	11/416346	OPTIMIZED SENSOR GEOMETRY FOR AN IMPLANTABLE GLUCOSE SENSOR	5/2/2006
DEXCOM.051C2	11/416375	TRANSCUTANEOUS ANALYTE SENSOR	5/2/2006
DEXCOM.012CP1C2	11/416734	BIOINTERFACE MEMBRANES INCORPORATING BIOACTIVE AGENTS	5/3/2006
DEXCOM.012CP1C1	11/416825	BIOINTERFACE MEMBRANES INCORPORATING BIOACTIVE AGENTS	5/3/2006
DEXCOM.051CP4	11/439559	ANALYTE SENSOR	5/23/2006
DEXCOM.051CP3	11/439630	ANALYTE SENSOR	5/23/2006
DEXCOM.051CP5	11/439800	ANALYTE SENSOR	5/23/2006
DEXCOM.61CP3CP1	11/445792	ANALYTE SENSOR	6/1/2006
DEXCOM.027CP1	11/498410	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	8/2/2006
DEXCOM.51CP3CP1	11/503367	ANALYTE SENSOR	8/10/2006

DEXCOM.27CP1CP2	11/515342	SYSTEMS AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	9/1/2006
DEXCOM.27CP1CP1	11/515443	SYSTEMS AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	9/1/2006
DEXCOM.088A	11/543396	ANALYTE SENSOR	10/4/2006
DEXCOM.088A3	11/543404	ANALYTE SENSOR	10/4/2006
DEXCOM.088A2	11/543490	ANALYTE SENSOR	10/4/2006
DEXCOM.038CP2	11/543539	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	10/4/2006
DEXCOM.038CP3	11/543683	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	10/4/2006
DEXCOM.038CP1	11/543707	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	10/4/2006
DEXCOM.038CP4	11/543734	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	10/4/2006
DEXCOM.8DCP2CC1	11/546157	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	10/10/2006
DEXCOM.012DV1	11/654135	POROUS MEMBRANES FOR USE WITH IMPLANTABLE DEVICES	1/17/2007
DEXCOM.058CP1	11/654140	MEMBRANES FOR AN ANALYTE SENSOR	1/17/2007
DEXCOM.058CP2	11/654327	MEMBRANES FOR AN ANALYTE SENSOR	1/17/2007
DEXCOM.021CP1	11/675063	ANALYTE SENSOR	2/14/2007
DEXCOM.51CP1CP1	11/681145	ANALYTE SENSOR	3/1/2007
DEXCOM.61CP2CP1	11/690752	TRANSCUTANEOUS ANALYTE SENSOR	3/23/2007
DEXCOM.088CP3	11/691424	ANALYTE SENSOR	3/26/2007
DEXCOM.088CP1	11/691426	ANALYTE SENSOR	3/26/2007
DEXCOM.088CP2	11/691432	ANALYTE SENSOR	3/26/2007
DEXCOM.088CP4	11/691466	ANALYTE SENSOR	3/26/2007
DEXCOM.38CP1CP1	11/692154	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	3/27/2007
DEXCOM.61CP2CP4	11/734178	TRANSCUTANEOUS ANALYTE SENSOR	4/11/2007
DEXCOM.61CP2CP2	11/734184	TRANSCUTANEOUS ANALYTE SENSOR	4/11/2007
DEXCOM.61CP2CP3	11/734203	TRANSCUTANEOUS ANALYTE SENSOR	4/11/2007

DEXCOM.093A	11/750907	ANALYTE SENSORS HAVING A SIGNAL-TO-NOISE RATIO SUBSTANTIALLY UNAFFECTED BY NON-CONSTANT NOISE	5/18/2007
DEXCOM.27CP1CP3	11/762638	SYSTEMS AND METHODS FOR REPLACING SIGNAL DATA ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	6/13/2007
DEXCOM.028DV1	11/763215	SILICONE COMPOSITION FOR BIOCOMPATIBLE MEMBRANE	6/14/2007
DEXCOM.051C4	11/797520	TRANSCUTANEOUS ANALYTE SENSOR	5/3/2007
DEXCOM.051C5	11/797521	TRANSCUTANEOUS ANALYTE SENSOR	5/3/2007
DEXCOM.061CP2C2	11/842139	TRANSCUTANEOUS ANALYTE SENSOR	8/21/2007
DEXCOM.061C1	11/842142	TRANSCUTANEOUS ANALYTE SENSOR	8/21/2007
DEXCOM.61CP2CPC	11/842143	TRANSCUTANEOUS ANALYTE SENSOR	8/20/2007
DEXCOM.061CP4C1	11/842146	ANALYTE SENSOR	8/20/2007
DEXCOM.061A1C1	11/842148	TRANSCUTANEOUS ANALYTE SENSOR	8/21/2007
DEXCOM.61CP3CPC	11/842149	TRANCUTANEOUS ANALYTE SENSOR	8/21/2007
DEXCOM.077C1	11/842151	ANALYTE SENSOR	8/21/2007
DEXCOM.061CP2C1	11/842154	TRANSCUTANEOUS ANALYTE SENSOR	8/21/2007
DEXCOM.093C1	11/842156	ANALYTE SENSORS HAVING A SIGNAL-TO-NOISE RATIO SUBSTANTILALLY UNAFFECTED BY NON-CONSTANT NOISE	8/21/2007
DEXCOM.51P3P1C1	11/842157	ANALYTE SENSOR	8/21/2007
DEXCOM.096A	11/855101	TRANSCUTANEOUS ANALYTE SENSOR	9/13/2007
DEXCOM.38CP1CP2	11/865572	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	10/1/2007
DEXCOM.025C1	11/865660	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	10/1/2007
DEXCOM.051A7C1	11/925603	TRANSCUTANEOUS ANALYTE SENSOR	10/26/2007
DEXCOM.8DV1CPD2	12/037812	ANALYTE MEASURING DEVICE	2/26/2008
DEXCOM.8DV1CPD1	12/037830	ANALYTE MEASURING DEVICE	2/26/2008

DEXCOM.107A	12/054953	ANALYTE SENSOR	3/25/2008
DEXCOM.88CP1CP2	12/055078	ANALYTE SENSOR	3/25/2008
DEXCOM.106A	12/055098	SYSTEM FOR PROCESSING SIGNALS FROM TWO IN VIVO ANALYTE SENSOR SENSORS	3/25/2008
DEXCOM.88CP1CP1	12/055114	ANALYTE SENSOR	3/25/2008
DEXCOM.88CP1CP3	12/055149	ANALYTE SENSOR	3/25/2008
DEXCOM.88CP1CP4	12/055203	ANALYTE SENSOR	3/25/2008
DEXCOM.88CP1CP5	12/055227	ANALYTE SENSOR	3/25/2008
DEXCOM.024C1D2	12/098353	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	4/4/2008
DEXCOM.024C1D1	12/098359	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	4/4/2008
DEXCOM.024C1D3	12/098627	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	4/7/2008
DEXCOM.051A6C3	12/101790	TRANSCUTANEOUS ANALYTE SENSOR	4/11/2008
DEXCOM.051A9C1	12/101806	TRANSCUTANEOUS ANALYTE SENSOR	4/11/2008
DEXCOM.051A6C2	12/101810	TRANSCUTANEOUS ANALYTE SENSOR	4/11/2008
DEXCOM.016DV1	12/102654	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	4/14/2008
DEXCOM.016DV2	12/102729	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	4/14/2008
DEXCOM.016DV3	12/102745	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	4/14/2008
DEXCOM.034DV1	12/103594	BIOINTERFACE WITH MACRO- AND MICRO-ARCHITECTURE	4/15/2008
DEXCOM.050C1	12/105227	TRANSCUTANEOUS MEDICAL DEVICE WITH VARIABLE STIFFNESS	4/17/2008
DEXCOM.038CP3C1	12/111062	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	4/28/2008
DEXCOM.063C2	12/113508	LOW OXYGEN IN VIVO ANALYTE SENSOR	5/1/2008
DEXCOM.063C1	12/113724	LOW OXYGEN IN VIVO ANALYTE SENSOR	5/1/2008

DEXCOM.094A2	12/133738	INTEGRATED MEDICAMENT DELIVERY DEVICE FOR USE WITH CONTINUOUS ANALYTE SENSOR	6/5/2008
DEXCOM.094A3	12/133761	INTEGRATED MEDICAMENT DELIVERY DEVICE FOR USE WITH CONTINUOUS ANALYTE SENSOR	6/5/2008
DEXCOM.094A4	12/133786	INTEGRATED MEDICAMENT DELIVERY DEVICE FOR USE WITH CONTINUOUS ANALYTE SENSOR	6/5/2008
DEXCOM.037CP1	12/133820	INTEGRATED MEDICAMENT DELIVERY DEVICE FOR USE WITH CONTINUOUS ANALYTE SENSOR	6/5/2008
DEXCOM.061A2DV1	12/137396	TRANSCUTANEOUS ANALYTE SENSOR	6/11/2008
DEXCOM.023RE	12/139305	ELECTRODE SYSTEMS FOR ELECTROCHEMICAL SENSORS	6/13/2008
DEXCOM.051A8C1	12/175391	TRANSCUTANEOUS ANALYTE SENSOR	7/17/2008
DEXCOM.032DV2	12/182008	INTEGRATED RECEIVER FOR CONTINUOUS ANALYTE SENSOR	7/29/2008
DEXCOM.032C1	12/182073	INTEGRATED RECEIVER FOR CONTINUOUS ANALYTE SENSOR	7/29/2008
DEXCOM.032DV3	12/182083	INTEGRATED RECEIVER FOR CONTINUOUS ANALYTE SENSOR	7/29/2008
DEXCOM.025C1C2	12/195191	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	8/20/2008
DEXCOM.025C1C1	12/195773	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	8/21/2008
DEXCOM.045DV1	12/247137	IMPLANTABLE ANALYTE SENSOR	10/7/2008
DEXCOM.051CP3DV	12/250918	ANALYTE SENSOR	10/14/2008
DEXCOM.029DV2	12/252952	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	10/16/2008
DEXCOM.029DV5	12/252967	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	10/16/2008
DEXCOM.029DV1	12/252996	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	10/16/2008
DEXCOM.029DV6	12/253064	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	10/16/2008
DEXCOM.029DV3	12/253120	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	10/16/2008
DEXCOM.029DV4	12/253125	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	10/16/2008

DEXCOM.098A	12/258235	SYSTEMS AND METHODS FOR PROCESSING SENSOR DATA	10/24/2008
DEXCOM.099A2	12/258318	SYSTEMS AND METHODS FOR PROCESSING SENSOR DATA	10/24/2008
DEXCOM.016CP1	12/258320	SYSTEMS AND METHODS FOR PROCESSING SENSOR DATA	10/24/2008
DEXCOM.099A1	12/258325	SYSTEMS AND METHODS FOR PROCESSING SENSOR DATA	10/24/2008
DEXCOM.27CP1CP4	12/258335	SYSTEMS AND METHODS FOR PROCESSING SENSOR DATA	10/24/2008
DEXCOM.099A	12/258345	SYSTEMS AND METHODS FOR PROCESSING SENSOR DATA	10/24/2008
DEXCOM.007C1DV1	12/260017	SENSOR HEAD FOR USE WITH IMPLANTABLE DEVICES	10/28/2008
DEXCOM.029C1	12/263993	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	11/3/2008
DEXCOM.38CPCPDV	12/264160	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	11/3/2008
DEXCOM.043DV1	12/264835	IMPLANTABLE ANALYTE SENSOR	11/4/2008
DEXCOM.88CPP5P6	12/267494	INTEGRATED DEVICE FOR CONTINUOUS IN VIVO ANALYTE DETECTION AND SIMULTANEOUS CONTROL OF AN INFUSION DEVICE	11/7/2008
DEXCOM.038CP5	12/267518	ANALYTE SENSOR	11/7/2008
DEXCOM.88CP1P1P	12/267525	ANALYTE SENSOR	11/7/2008
DEXCOM.88P1P1P2	12/267531	ANALYTE SENSOR	11/7/2008
DEXCOM.016CP2	12/267542	ANALYTE SENSOR	11/7/2008
DEXCOM.88CPP5P4	12/267544	ANALYTE SENSOR	11/7/2008
DEXCOM.88CPP5P5	12/267545	ANALYTE SENSOR	11/7/2008
DEXCOM.88CPP5P3	12/267546	ANALYTE SENSOR	11/7/2008
DEXCOM.88CPP5P2	12/267547	ANALYTE SENSOR	11/7/2008
DEXCOM.88CPP5P1	12/267548	ANALYTE SENSOR	11/7/2008
DEXCOM.051A12C1	12/273359	TRANSCUTANEOUS ANALYTE SENSOR	11/18/2008
DEXCOM.051C6	12/329496	TRANSCUTANEOUS ANALYTE SENSOR	12/5/2008
DEXCOM.038CP2C1	12/335403	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	12/15/2008
DEXCOM.027DV1	12/353787	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	1/14/2009

DEXCOM.027DV2	12/353799	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	1/14/2009
DEXCOM.061C2	12/353870	TRANSCUTANEOUS ANALYTE SENSOR	1/14/2009
DEXCOM.051C7	12/359207	TRANSCUTANEOUS ANALYTE SENSOR	1/23/2009
DEXCOM.100A	12/362194	CONTINUOUS CARDIAC MARKER SENSOR SYSTEM	1/29/2009
DEXCOM.061CP2C3	12/364786	TRANSCUTANEOUS ANALYTE SENSOR	2/3/2009
DEXCOM.101A	12/365683	CONTINUOUS MEDICAMENT SENSOR SYSTEM FOR IN VIVO USE	2/4/2009
DEXCOM.102A2	12/390205	SYSTEMS AND METHODS FOR CUSTOMIZING DELIVERY OF SENSOR DATA	2/20/2009
DEXCOM.102A3	12/390290	SYSTEMS AND METHODS FOR BLOOD GLUCOSE MONITORING AND ALERT DELIVERY	2/20/2009
DEXCOM.102A1	12/390304	SYSTEMS AND METHODS FOR PROCESSING, TRANSMITTING AND DISPLAYING SENSOR DATA	2/20/2009
DEXCOM.061DV1	12/391148	TRANSCUTANEOUS ANALYTE SENSOR	2/23/2009
DEXCOM.051C10	12/393887	TRANSCUTANEOUS ANALYTE SENSOR	2/26/2009
DEXCOM.104A2	12/413166	POLYMER MEMBRANES FOR CONTINUOUS ANALYTE SENSORS	3/27/2009
DEXCOM.104A1	12/413231	POLYMER MEMBRANES FOR CONTINUOUS ANALYTE SENSORS	3/27/2009
DEXCOM.029DV8	12/424391	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	4/15/2009
DEXCOM.029DV7	12/424403	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	4/15/2009
DEXCOM.061A1C2	12/437436	TRANSCUTANEOUS ANALYTE SENSOR	5/7/2009
DEXCOM.029DV9	12/509396	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	7/24/2009
DEXCOM.075DV1	12/511982	SILICONE BASED MEMBRANES FOR USE IN IMPLANTABLE GLUCOSE SENSORS	7/29/2009
DEXCOM.088CP4C1	12/535620	ANALYTE SENSOR	8/4/2009
DEXCOM.037DV1	12/536852	INTEGRATED DELIVERY DEVICE FOR CONTINUOUS GLUCOSE SENSOR	8/6/2009

DEXCOM.095A	12/562011	PARTICLE-CONTAINING MEMBRANE AND PARTICULATE ELECTRODE FOR ANALYTE SENSORS	9/17/2009
DEXCOM.029DV11	12/565156	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	9/23/2009
DEXCOM.029DV12	12/565166	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	9/23/2009
DEXCOM.029DV13	12/565173	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	9/23/2009
DEXCOM.029DV10	12/565180	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	9/23/2009
DEXCOM.029DV14	12/565199	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	9/23/2009
DEXCOM.032DV1DV	12/565205	INTEGRATED RECEIVER FOR CONTINUOUS ANALYTE SENSOR	9/23/2009
DEXCOM.029DV15	12/565231	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	9/23/2009
DEXCOM.029DV16	12/577668	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	10/12/2009
DEXCOM.029C4	12/577690	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	10/12/2009
DEXCOM.029DV17	12/577691	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	10/12/2009
DEXCOM.027C1	12/579339	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	10/14/2009
DEXCOM.027C3	12/579357	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	10/14/2009
DEXCOM.027C2	12/579363	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	10/14/2009
DEXCOM.027C7	12/579374	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	10/14/2009
DEXCOM.027C4	12/579385	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	10/14/2009
DEXCOM.027C5	12/579388	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	10/14/2009
DEXCOM.027C6	12/579392	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	10/14/2009

DEXCOM.044DV1	12/608872	IMPLANTABLE ANALYTE SENSOR	10/29/2009
DEXCOM.040DV1	12/610127	COMPOSITE MATERIAL FOR IMPLANTABLE DEVICE	10/30/2009
DEXCOM.061CP3C1	12/610866	ANALYTE SENSOR	11/2/2009
DEXCOM.038C1	12/619502	CALIBRATION TECHNIQUES FOR A CONTINUOUS ANALYTE SENSOR	11/16/2009
DEXCOM.104C1	12/628095	POLYMER MEMBRANES FOR CONTINUOUS ANALYTE SENSORS	11/30/2009
DEXCOM.088CP3C2	12/630628	ANALYTE SENSOR	12/3/2009
DEXCOM.006C1C1	12/633578	MEMBRANE FOR USE WITH IMPLANTABLE DEVICES	12/8/2009
DEXCOM.025C1C3	12/633654	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	12/8/2009
DEXCOM.025C1C6	12/636473	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	12/11/2009
DEXCOM.025C1C9	12/636494	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	12/11/2009
DEXCOM.025C1C8	12/636540	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	12/11/2009
DEXCOM.025C1C5	12/636551	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	12/11/2009
DEXCOM.025C1C7	12/636574	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	12/11/2009
DEXCOM.025C1C4	12/636584	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	12/11/2009
DEXCOM.016C2	12/639746	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	12/16/2009
DEXCOM.026C1	12/639829	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	12/16/2009
DEXCOM.008DV1C3	12/645097	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	12/22/2009
DEXCOM.008DV1C2	12/645270	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	12/22/2009

DEXCOM.053C2	12/683724	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA FOR SENSOR CALIBRATION	1/7/2010
DEXCOM.053C1	12/683755	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA FOR SENSOR CALIBRATION	1/7/2010
DEXCOM.010DV1C1	12/688737	TECHNIQUES TO IMPROVE POLYURETHANE MEMBRANES FOR IMPLANTABLE GLUCOSE SENSORS	1/15/2010
DEXCOM.021C1C1	12/688763	OXYGEN ENHANCING MEMBRANE SYSTEMS FOR IMPLANTABLE DEVICES	1/15/2010
DEXCOM.026DV1	12/690792	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	1/20/2010
DEXCOM.058C1	12/691617	CELLULOSIC-BASED INTERFERENCE DOMAIN FOR AN ANALYTE SENSOR	1/21/2010
DEXCOM.8DCP2CCC	12/696003	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	1/28/2010
DEXCOM.088CP2C1	12/713607	ANALYTE SENSOR	2/26/2010
DEXCOM.104A1CP1	12/718299	POLYMER MEMBRANES FOR CONTINUOUS ANALYTE SENSORS	3/5/2010
DEXCOM.104A1CP2	12/718332	POLYMER MEMBRANES FOR CONTINUOUS ANALYTE SENSORS	3/5/2010
DEXCOM.051A6C4	12/728032	TRANSCUTANEOUS ANALYTE SENSOR	3/19/2010
DEXCOM.051A6C5	12/728060	TRANSCUTANEOUS ANALYTE SENSOR	3/19/2010
DEXCOM.051A6C6	12/728061	TRANSCUTANEOUS ANALYTE SENSOR	3/19/2010
DEXCOM.051A6C7	12/728082	TRANSCUTANEOUS ANALYTE SENSOR	3/19/2010
DEXCOM.51A8C1C1	12/729035	TRANSCUTANEOUS ANALYTE SENSOR	3/22/2010
DEXCOM.51A8C1C2	12/729048	TRANSCUTANEOUS ANALYTE SENSOR	3/22/2010
DEXCOM.051A10C1	12/729058	TRANSCUTANEOUS ANALYTE SENSOR	3/22/2010
DEXCOM.016C3	12/730058	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	3/23/2010
DEXCOM.051A10C2	12/730072	TRANSCUTANEOUS ANALYTE SENSOR	3/23/2010

DEXCOM.016C4	12/730077	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	3/23/2010
DEXCOM.016C6	12/730108	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	3/23/2010
DEXCOM.016C8	12/730123	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	3/23/2010
DEXCOM.016C9	12/730132	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	3/23/2010
DEXCOM.016C7	12/730144	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	3/23/2010
DEXCOM.016C5	12/730152	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	3/23/2010
DEXCOM.029C5	12/731046	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	3/24/2010
DEXCOM.032C1C1	12/731965	INTEGRATED RECEIVER FOR CONTINUOUS ANALYTE SENSOR	3/25/2010
DEXCOM.027C8	12/731980	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	3/25/2010
DEXCOM.27CPCPC1	12/732010	SYSTEMS AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	3/25/2010
DEXCOM.27CPCP3C	12/732097	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	3/25/2010
DEXCOM.038CP2CC	12/748024	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	3/26/2010
DEXCOM.135A	12/748069	METHODS AND SYSTEMS FOR PROMOTING GLUCOSE MANAGEMENT	3/26/2010
DEXCOM.016C10	12/748144	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	3/26/2010
DEXCOM.053C3	12/748154	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA FOR SENSOR CALIBRATION	3/26/2010
DEXCOM.061A1C3	12/749139	TRANSCUTANEOUS ANALYTE SENSOR	3/29/2010

DEXCOM.38CPCPC2	12/749265	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	3/29/2010
DEXCOM.051A9C3	12/749981	TRANSCUTANEOUS ANALYTE SENSOR	3/30/2010
DEXCOM.038C3	12/760358	CALIBRATION TECHNIQUES FOR CONTINUOUS ANALYTE SENSOR	4/14/2010
DEXCOM.038C2	12/760432	CALIBRATION TECHNIQUES FOR A CONTINUOUS ANALYTE SENSOR	4/14/2010
DEXCOM.8DV1C2C1	12/763013	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	4/19/2010
DEXCOM.8DV1C2C2	12/763016	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	4/19/2010
DEXCOM.138A	12/770618	PERFORMANCE REPORTS ASSOCIATED WITH CONTINUOUS SENSOR DATA FROM MULTIPLE ANALYSIS TIME PERIODS	4/29/2010
DEXCOM.016C12	12/772842	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	5/3/2010
DEXCOM.016C11	12/772849	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	5/3/2010
DEXCOM.051A5C1	12/775315	TRANSCUTANEOUS ANALYTE SENSOR	5/6/2010
DEXCOM.051A12C4	12/780606	TRANSCUTANEOUS ANALYTE SENSOR	5/14/2010
DEXCOM.051A12C2	12/780723	TRANSCUTANEOUS ANALYTE SENSOR	5/14/2010
DEXCOM.051A12C3	12/780725	TRANSCUTANEOUS ANALYTE SENSOR	5/14/2010
DEXCOM.051A12C5	12/780739	TRANSCUTANEOUS ANALYTE SENSOR	5/14/2010
DEXCOM.051A12C6	12/780759	TRANSCUTANEOUS ANALYTE SENSOR	5/14/2010
DEXCOM.027C9	12/787217	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	5/25/2010
DEXCOM.016C13	12/788125	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	5/26/2010
DEXCOM.027C10	12/789153	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	5/27/2010

DEXCOM.027C11	12/791686	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	6/1/2010
DEXCOM.027C12	12/791791	SYSTEM AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	6/1/2010
DEXCOM.88PP5P5P	12/828967	HOUSING FOR AN INTRAVASCULAR SENSOR	7/1/2010
DEXCOM.156A	12/829264	ANALYTE SENSOR	7/1/2010
DEXCOM.111A	12/829296	ANALYTE SENSORS AND METHODS OF MANUFACTURING SAME	7/1/2010
DEXCOM.111A3	12/829306	ANALYTE SENSORS AND METHODS OF MANUFACTURING SAME	7/1/2010
DEXCOM.111A2	12/829318	ANALYTE SENSORS AND METHODS OF MANUFACTURING SAME	7/1/2010
DEXCOM.157A3	12/829337	CONTINUOUS ANALYTE SENSORS AND METHODS OF MAKING SAME	7/1/2010
DEXCOM.157A	12/829339	CONTINUOUS ANALYTE SENSORS AND METHODS OF MAKING SAME	7/1/2010
DEXCOM.157A2	12/829340	CONTINUOUS ANALYTE SENSORS AND METHODS OF MAKING SAME	7/1/2010
DEXCOM.38CPCPC1	12/838691	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	7/19/2010
DEXCOM.038CP4RE	12/839260	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	7/19/2010
DEXCOM.061CP2C4	12/853235	TRANSCUTANEOUS ANALYTE SENSOR	8/9/2010
DEXCOM.096C1	12/869996	TRANSCUTANEOUS ANALYTE SENSOR	8/27/2010
DEXCOM.038C1C2	12/874031	CALIBRATION TECHNIQUES FOR A CONTINUOUS ANALYTE SENSOR	9/1/2010
DEXCOM.038C1C1	12/874045	CALIBRATION TECHNIQUES FOR A CONTINUOUS ANALYTE SENSOR	9/1/2010
DEXCOM.102A1C3	12/880015	SYSTEMS AND METHODS FOR PROCESSING, TRANSMITTING AND DISPLAYING SENSOR DATA	9/10/2010
DEXCOM.102A1C2	12/880026	SYSTEMS AND METHODS FOR PROCESSING, TRANSMITTING AND DISPLAYING SENSOR DATA	9/10/2010
DEXCOM.102A1C1	12/880031	SYSTEMS AND METHODS FOR PROCESSING, TRANSMITTING AND DISPLAYING SENSOR DATA	9/10/2010
DEXCOM.159A	12/893850	TRANSCUTANEOUS ANALYTE SENSOR	9/29/2010

DEXCOM.38PPDC	12/916289	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	10/29/2010
DEXCOM.027D2C1	13/014910	SYSTEM AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	1/27/2011
DEXCOM.027D2C2	13/014929	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	1/27/2011
DEXCOM.027D2D1	13/015208	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	1/27/2011
DEXCOM.027D2D2	13/015245	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	1/27/2011
DEXCOM.011D3C1	13/015950	OPTIMIZED SENSOR GEOMETRY FOR AN IMPLANTABLE GLUCOSE SENSOR	1/28/2011
DEXCOM.027C15	13/023776	SYSTEMS AND METHODS OF REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	2/9/2011
DEXCOM.027C14	13/023835	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	2/9/2011
DEXCOM.027C13	13/023879	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	2/9/2011
DEXCOM.027C16	13/024076	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	2/9/2011
DEXCOM.137A	13/026163	IMPROVED RECEIVERS FOR ANALYZING AND DISPLAYING SENSOR DATA	2/11/2011
DEXCOM.063C4	13/031063	LOW OXYGEN IN VIVO ANALYTE SENSOR	2/18/2011
DEXCOM.051A1C1	13/077884	TRANSCUTANEOUS ANALYTE SENSOR	3/31/2011
DEXCOM.027P2D1	13/080587	SYSTEMS AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	4/5/2011
DEXCOM.051A1C2	13/086160	TRANSCUTANEOUS ANALYTE SENSOR	4/13/2011
DEXCOM.032C3	13/092538	INTEGRATED RECEIVER FOR CONTINUOUS ANALYTE SENSOR	4/22/2011
DEXCOM.061P2C5	13/116871	TRANSCUTANEOUS ANALYTE SENSOR	5/26/2011

DEXCOM.025C11	13/118915	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	5/31/2011
DEXCOM.026D2	13/149005	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	5/31/2011
DEXCOM.025C12	13/149035	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	5/31/2011
DEXCOM.051A6P1	13/157031	TRANSCUTANEOUS ANALYTE SENSOR	6/9/2011
DEXCOM.016DV3RX	90/010988	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	5/10/2010
DEXCOM.016DV2RX	90/011031	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	6/14/2010
DEXCOM.006ARX	90/011067	MEMBRANE FOR USE WITH IMPLANTABLE DEVICES	6/25/2010
DEXCOM.006C1RX	90/011080	MEMBRANE FOR USE WITH IMPLANTABLE DEVICES	7/2/2010
DEXCOM.051A7RX	90/011086	METHODS AND SYSTEMS FOR INSERTING A TRANSCUTANEOUS ANALYTE SENSOR	7/8/2010
DEXCOM.010X	90/011329	TECHNIQUES TO IMPROVE POLYURETHANE MEMBRANES FOR IMPLANTABLE GLUCOSE SENSORS	11/12/2010
DEXCOM.012X	90/011330	POROUS MEMBRANES FOR USE WITH IMPLANTABLE DEVICES	11/12/2010
DEXCOM.061P3X	90/011333	ANALYTE SENSOR	11/15/2010
DEXCOM.008D1C1X	90/011345	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	11/19/2010
DEXCOM.051X	90/011351	TRANSCUTANEOUS ANALYTE SENSOR	11/22/2010
DEXCOM.8D1C3X	90/011466	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	1/31/2011
DEXCOM.016AX	90/011467	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	1/31/2011
DEXCOM.63C2X	90/011468	LOW OXYGEN IN VIVO ANALYTE SENSOR	2/1/2011
DEXCOM.063X2	90/011610	LOW OXYGEN IN VIVO ANALYTE SENSOR	3/31/2011

DEXCOM.016X4	90/011635	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	4/8/2011
DEXCOM.031X1	90/011645	SYSTEMS AND METHODS FOR IMPROVING ELECTROCHECMICAL ANALYTE SENSORS	4/14/2011
DEXCOM.051A5X1	90/011663	TRANSCUTANEOUS ANALYTE SENSOR	4/29/2011
DEXCOM.038X1	90/011671	CALIBRATION TECHNIQUES FOR A CONTINUOUS ANALYTE SENSOR	5/5/2011
DEXCOM.008X	90/011683	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	5/10/2011
DEXCOM.024X2	90/011721	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	5/31/2011
DEXCOM.008X2	90/011722	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	5/31/2011
DEXCOM.025RX	95/001038	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	4/17/2008
DEXCOM.024RX	95/001039	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	4/17/2008

Conclusion

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns that might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: June 20, 2011

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
90/011,466	01/31/2011	7792562	ADCI-GEN50	8367

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EXAMINER	
ART UNIT	PAPER NUMBER

DATE MAILED: 04/18/2011

Please find below and/or attached an Office communication concerning this application or proceeding.

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THIRD PARTY REQUESTER'S CORRESPONDENCE ADDRESS

Date: 4-18-11

Peter A. Socarras
BOZICEVIC FIELD & FRANCIS LLP
1900 University Ave., Suite 200
East Palo Alto, CA 94303

EX PARTE REEXAMINATION COMMUNICATION TRANSMITTAL FORM

REEXAMINATION CONTROL NO. : 90011466
PATENT NO. : 7792562
ART UNIT : 3993

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified ex parte reexamination proceeding (37 CFR 1.550(f)).

Where this copy is supplied after the reply by requester, 37 CFR 1.535, or the time for filing a reply has passed, no submission on behalf of the ex parte reexamination requester will be acknowledged or considered (37 CFR 1.550(g)).

Order Granting / Denying Request For Ex Parte Reexamination	Control No.	Patent Under Reexamination	
	90/011,466	7792562	
	Examiner	Art Unit	
	BEVERLY M. FLANAGAN	3993	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

The request for *ex parte* reexamination filed *31 January 2011* has been considered and a determination has been made. An identification of the claims, the references relied upon, and the rationale supporting the determination are attached.

Attachments: a)☐ PTO-892, b)☒ PTO/SB/08, c)☐ Other: _____

1. ☒ The request for *ex parte* reexamination is GRANTED.

RESPONSE TIMES ARE SET AS FOLLOWS:

For Patent Owner's Statement (Optional): TWO MONTHS from the mailing date of this communication (37 CFR 1.530 (b)). **EXTENSIONS OF TIME ARE GOVERNED BY 37 CFR 1.550(c).**

For Requester's Reply (optional): TWO MONTHS from the **date of service** of any timely filed Patent Owner's Statement (37 CFR 1.535). **NO EXTENSION OF THIS TIME PERIOD IS PERMITTED.** If Patent Owner does not file a timely statement under 37 CFR 1.530(b), then no reply by requester is permitted.

2. ☐ The request for *ex parte* reexamination is DENIED.

This decision is not appealable (35 U.S.C. 303(c)). Requester may seek review by petition to the Commissioner under 37 CFR 1.181 within ONE MONTH from the mailing date of this communication (37 CFR 1.515(c)). **EXTENSION OF TIME TO FILE SUCH A PETITION UNDER 37 CFR 1.181 ARE AVAILABLE ONLY BY PETITION TO SUSPEND OR WAIVE THE REGULATIONS UNDER 37 CFR 1.183.**

In due course, a refund under 37 CFR 1.26 (c) will be made to requester:

a) ☐ by Treasury check or,

b) ☐ by credit to Deposit Account No. _____, or

c) ☐ by credit to a credit card account, unless otherwise notified (35 U.S.C. 303(c)).

cc:Requester (if third party requester)

DECISION ON REQUEST FOR REEXAMINATION

A substantial new question of patentability affecting claims 1, 5, 9, 15, 20-22, 25-28, 32, 36, 42, 47-49, 52, 53, 57, 61, 67, 72-74, 77-80, 84, 88, 94, 99-101, 104-107, 111, 120, 125-127 and 130-132 of United States Patent Number 7,792,562 is raised by the request for *ex parte* reexamination.

Extensions of time under 37 CFR 1.136(a) will not be permitted in these proceedings because the provisions of 37 CFR 1.136 apply only to "an applicant" and not to parties in a reexamination proceeding. Additionally, 35 U.S.C. 305 requires that *ex parte* reexamination proceedings "will be conducted with special dispatch" (37 CFR 1.550(a)). Extensions of time in *ex parte* reexamination proceedings are provided for in 37 CFR 1.550(c).

Service of Papers

After the filing of a request for reexamination by a third party requester, any document filed by either the patent owner or the third party requester must be served on the other party (or parties where two or more third party requester proceedings are merged) in the reexamination proceeding in the manner provided in 37 C.F.R. 1.248. See 37 C.F.R. 1.550(f).

Waiver of Right to File Patent Owner Statement

In a telephone interview on February 25, 2001, patent owner agreed to waive its right to file a patent owner's statement under 35 U.S.C. § 304 in the event reexamination was ordered for U.S. Patent No. 7,792,562.

Amendment in Reexamination Proceedings

Patent owner is notified that any proposed amendment to the specification and/or claims in this reexamination proceeding must comply with 37 C.F.R. 1.530(d)-(j), must be formally presented pursuant to 37 C.F.R. 1.52(a) and (b), and must contain any fees required by 37 C.F.R. 1.20(c).

Submissions

In order to ensure full consideration of any amendments, affidavits or declarations or other documents as evidence of patentability, such documents must be submitted in response to the first Office action on the merits (which does not result in a close of prosecution). Submissions after the second Office action on the merits, which is intended to be a final action, will be governed by the requirements of 37 C.F.R. 1.116, after final rejection and by 37 C.F.R. 41.33 after appeal, which will be strictly enforced.

Notification of Concurrent Proceedings

The patent owner is reminded of the continuing responsibility under 37 C.F.R. 1.565(a) to apprise the Office of any litigation activity, or other prior or concurrent

proceeding, involving U.S. Patent No. 7,792,562 throughout the course of this reexamination proceeding. Likewise, if present, the third party requester is also reminded of the ability to similarly apprise the Office of any such activity or proceeding throughout the course of this reexamination proceeding. See MPEP §§ 2207, 2282 and 2286.

Substantial New Question

A substantial new question of patentability (SNQ) is based on the following newly submitted printed publications:

Kusano, H., Glucose enzyme electrode with percutaneous interface which operates independently of dissolved oxygen, *Clin. Phys. Physiol. Meas.*, vol. 10, 1:1-9 (1989) (hereinafter "Kusano").

A substantial new question of patentability (SNQ) is also based on the following previously-cited printed publications:

Allen, U.S. Patent No. 5,322,063 (hereinafter "Allen");

Mastrototaro et al., "An electroenzymatic glucose sensor fabricated on a flexible substrate," *Sensors and Actuators B*, 5:139-44 (1991) (hereinafter "Mastrototaro");

Moatti-Sirat et al., Towards continuous glucose monitoring: in vivo evaluation of a miniaturized glucose sensor implanted for several days in rat subcutaneous tissue, *Diabetologia*, 35:224-230 (1992) (hereinafter "Moatti-Sirat"); and

Csöregi et al., Design, Characterization and One-Point in Vivo Calibration of a Subcutaneously Implanted Glucose Electrode, *Analytical Chemistry*, 66(19):3131-3138 (October 1, 1994) (hereinafter "Csöregi").

On November 2, 2002, Public Law 107-273 was enacted. Title III, Subtitle A, Section 13105, part (a) of the Act revised the reexamination statute by adding the following new last sentence to 35 U.S.C. 303(a) and 312(a):

> "The existence of a substantial new question of patentability is not precluded by the fact that a patent or printed publication was previously cited by or to the Office or considered by the Office."

For any reexamination ordered on or after November 2, 2002, the effective date of the statutory revision, reliance on previously cited/considered art, i.e., "old art," does not necessarily preclude the existence of a substantial new question of patentability (SNQ) that is based exclusively on that old art. Rather, determinations on whether a SNQ exists in such an instance shall be based upon a fact-specific inquiry. In the instant case, Allen, Mastrototaro, Moatti-Sirat and Csöregi were all cited in the previous examination, but were not applied to the claims. In addition, none of Mastrototaro, Moatti-Sirat and Csöregi was considered in combination Kusano, as is proposed in the instant request. This situation provides the new light under which the Allen, Mastrototaro, Moatti-Sirat and Csöregi references are considered.

Documents Not Considered

Requester lists a Clarke publication (Clarke et al., Evaluating Clinical Accuracy of Systems for Self-Monitoring of Blood Glucose, *Diabetes Care*, Vol. 10, No. 5:622-628 (1987)) on the information disclosure statement provided with the request. However, requester does not propose any SNQ with respect to Clarke. Accordingly, this publication was not considered by the examiner in considering whether an SNQ exists.

A discussion of the specifics follows:

The Allen Reference

It is agreed that the Allen reference raises a SNQ as to claims 1, 5, 9, 15, 20-22, 25-28, 32, 36, 42, 47-49, 52, 53, 57, 61, 67, 72-74, 77-80, 84, 88, 94, 99-101, 104-107, 111, 120, 125-127 and 130-132 of U.S. Patent No. 7,792,562.

In regard to claims 1, 15, 21, 22, 25-28, 48, 49, 52, 53, 67, 77-80, 100, 101, 104-107, 120, 126, 127 and 130-132, it is agreed that Allen teaches a device for measuring glucose concentration in a host comprised of a sensor 10 having a distal portion 11 that includes sensor elements 12-14 that are connected through leads 15 to contacts 16 (see Figs. 1 and 2 and col. 5, lines 7-15). Contacts 16 are connected with a suitable monitoring device (not shown) that receives signals and translates this information into a determination of the glucose level detected (see col. 5, lines 11-15). The distal portion 11 is implanted subcutaneously into the body and the implanted

sensor elements 12-14 are covered with a membrane 20 that controls the rate of diffusion of glucose and oxygen from the surrounding body tissue to the area of the sensor elements (see Figs. 1 and 2 and col. 5, lines 35-39). Allen teaches in vitro testing of the device, where a computer-controlled system was built to automatically expose 16 sensors provided with the membranes to an array of four different glucose concentrations: 0, 100, 200 and 400 mg/dL and four different oxygen concentrations: 1, 2, 5 and 20.9% oxygen (approximately 7-150 mmHg) (see col. 9, lines 50-56). Allen teaches that it was found that the sensors responded linearly to glucose concentrations ranging from 0-100 mg/dL (see col. 9, lines 57-60). Allen also teaches that varying the oxygen concentration of the calibration solution between 1 and 20.9% had no effect on the output of the sensor, even at high glucose concentrations (see col. 9, lines 63-66). ***With further respect to claim 80***, Allen also teaches that the 90% response time for a change in the glucose concentration from 0 to 100 mg/dL was less than 90 seconds (see col. 9, line 63 through col. 10, line 2). ***With further respect to claim 107 and in regard to claims 9, 36, 61 and 88***, Allen also teaches that the membrane is formed from a hydrophilic polyurethane (see col. 5, lines 44-45).

In regard to claims 5, 32, 57, 84 and 111, Allen teaches that glucose oxidase 19 is deposited on the working electrode and all three sensor/electrodes are then covered with the membrane 20 (see Fig. 2 and col. 5, lines 28-31). ***In regard to claims 20, 47, 72, 99 and 125***, Allen teaches that the sensor is able to function for at least 3 days (see col. 10, lines 3-9).

The teachings identified above were present in the prosecution of the application which became U.S. Patent No. 7,792,562. However, they were not applied to the claims. There is a substantial likelihood that a reasonable examiner would consider these teachings important in deciding whether or not the claim is patentable. Accordingly, Allen raises a substantial new question of patentability as to claims 1, 5, 9, 15, 20-22, 25-28, 32, 36, 42, 47-49, 52, 53, 57, 61, 67, 72-74, 77-80, 84, 88, 94, 99-101, 104-107, 111, 120, 125-127 and 130-132, which question has not been decided in a previous examination of U.S. Patent No. 7,792,562.

The Moatti-Sirat Reference

It is agreed that the Moatti-Sirat reference raises a SNQ as to claims 15, 20-22, 42, 47-49, 67, 72-74, 94, 99-101, 120 and 125-127 of U.S. Patent No. 7,792,562.

In regard to claims 15, 42, 67, 94 and 120, it is agreed that Moatti-Sirat teaches a glucose sensor for implantation in the subcutaneous tissue of an animal having a membrane disposed over the glucose sensor (see pages 224-225). Moatti-Sirat also teaches that the electrode is configured to measure a current produced by the electrode with substantial linearity up to a glucose concentration of 22 mM (400 mg/dL) (see Table 1 and page 225). Moatti-Sirat teaches experimental results that show that 99% of the time, values fall within a Zone A, which deviates no more than 20% from the reference (see Fig. 6 and page 227). ***In regard to claims 20- 22,47-49, 72-74, 99-101 and 125-127***, Moatti-Sirat teaches implantation of the device for at least 10 days (see pages 224 and 228).

The teachings identified above were present in the prosecution of the application which became U.S. Patent No. 7,792,562. However, they were not applied to the claims. There is a substantial likelihood that a reasonable examiner would consider these teachings important in deciding whether or not the claim is patentable. Accordingly, Moatti-Sirat raises a substantial new question of patentability as to claims 15, 20-22, 42, 47-49, 67, 72-74, 94, 99-101, 120 and 125-127, which question has not been decided in a previous examination of U.S. Patent No. 7,792,562.

The Csöregi Reference

It is agreed that the Csöregi reference raises a SNQ as to claims 25, 52, 77, 104 and 130 of U.S. Patent No. 7,792,562.

In regard to claims 25, 52, 77, 104 and 130, it is agreed that Csöregi teaches a device for measuring glucose concentration in a host, where the sensors are configured for single-point recalibration. Csöregi teaches that the stability observed and the existence of a valid zero point in the presence of interferants suggested that the sensor could be used in vivo for 72 hours and be tested/recalibrated in vivo through a single-point calibration (by withdrawing only a single sample of blood for independent analysis) (see page 3136).

The teachings identified above were present in the prosecution of the application which became U.S. Patent No. 7,792,562. However, they were not applied to the claims. There is a substantial likelihood that a reasonable examiner would consider these teachings important in deciding whether or not the claim is patentable.

Accordingly, Csöregi raises a substantial new question of patentability as to claims 25, 52, 77, 104 and 130 which question has not been decided in a previous examination of U.S. Patent No. 7,792,562.

The Kusano Reference

It is agreed that the Kusano reference raises a SNQ as to claims 1, 5, 9, 26, 27, 28, 32, 36, 53, 57, 61, 78-80, 84, 88, 105-107, 111, 131 and 132 of U.S. Patent No. 7,792,562.

In regard to claims 1, 27, 28, 53, 79, 80, 106, 107 and 132, it is agreed that Kusano teaches a device for measuring glucose concentration in a host comprised of an electrode surface operably connected to an electronic circuit and configured to continuously measures a signal indicative of a glucose concentration in a host for a period of time (see pages 2-3). Kusano teaches a membrane located over at least a portion of the electrode surface, the membrane comprising a layer configured to control a flux of oxygen and glucose (see pages 2-3). Kusano also teaches that the sensor system measures glucose concentrations from 0 to 500 mg/dL, in a fluid with an oxygen concentration ranging from 0 kPa (0 mmHg) to 20.5 kPa (154 mmHg) (see pages 6-7). Kusano also teaches that oxygen concentration had no effect on electrode response (see pages 6-7 and Fig 8). Kusano also teaches a linear current measurement up to 500 mg/dL and a negligible drop in sensor output as the Po_2 is varied from 0 kPa (0 mmHg) to 20.5 kPa (154 mmHg) (see Fig. 8 and page 8).

In regard to claims 5, 32, 57, 84 and 111, Kusano teaches an enzyme layer of immobilized glucose oxidase (see page 3). ***With further respect to claim 107 and in regard to claims 9, 36, 61 and 88***, Kusano teaches forming the membrane from polyurethane (see page 3 and Fig. 2). ***With further respect to claim 28 and in regard to claims 26, 78, 105 and 131***, Kusano teaches that although the sensors are tested *in vitro*, they are designed and intended for *in vivo* implantation.

The teachings identified above were not present in the prosecution of the application which became U.S. Patent No. 7,792,562. Accordingly, there is a substantial likelihood that a reasonable examiner would consider these teachings important in deciding whether or not the claim is patentable. Thus, Kusano raises a substantial new question of patentability as to claims 1, 5, 9, 26, 27, 28, 32, 36, 53, 57, 61, 78-80, 84, 88, 105-107, 111, 131 and 132 which question has not been decided in a previous examination of U.S. Patent No. 7,792,562.

The Mastrototaro Reference

It is agreed that the Mastrototaro reference raises a SNQ as to claims 1, 5, 9, 15, 20-22 and 25-27 of U.S. Patent No. 7,792,562.

In regard to claims 1, 5, 9, 15, 20-22 and 25-27, it is agreed that Mastrototaro teaches a device for measuring glucose concentration in a host comprised of a sensor operably connected to an electronic circuit and configured to continuously measure a signal indicative of a glucose concentration in a host for a period of time (see pages 140-143). Mastrototaro also teaches that the entire sensor is covered with a

differentially permeable biocompatible membrane that is two to three orders of magnitude more permeable to oxygen than glucose (see page 141). Mastrototaro also teaches that it is important to correlate an *in vitro* calibration of the sensors prior to implantation to *in vivo* response (see page 143).

The teachings identified above were present in the prosecution of the application which became U.S. Patent No. 7,792,562. However, they were not applied to the claims. There is a substantial likelihood that a reasonable examiner would consider these teachings important in deciding whether or not the claim is patentable. Accordingly, Mastrototaro raises a substantial new question of patentability as to claims 1, 5, 9, 15, 20-22 and 25-27 which question has not been decided in a previous examination of U.S. Patent No. 7,792,562.

Scope of Reexamination

Since requester did not request reexamination of claims 2-4, 6-8, 10-14, 16-19, 23, 24, 29-31, 33-35, 37-41, 43-46, 50, 51, 54-56, 58-60, 62-66, 68-71, 75, 76, 81-83, 85-87, 89-93, 95-98, 102, 103, 108-110, 112-119, 121-124, 128 and 129 and did not assert the existence of a substantial new question of patentability (SNQP) for such claims (see 35 U.S.C. § 311(b)(2); see also 37 CFR 1.915b and 1.923), such claims will not be reexamined. This matter was squarely addressed in *Sony Computer Entertainment America Inc., et al. v. Jon W. Dudas*, Civil Action No. 1:05CV1447 (E.D.Va. May 22, 2006), Slip Copy, 2006 WL 1472462. (Not Reported in F.Supp.2d.) The District Court upheld the Office's discretion to not reexamine claims in an *inter*

partes reexamination proceeding other than those claims for which reexamination had specifically been requested. The Court stated:

> To be sure, a party may seek, and the PTO may grant, *inter partes* review of each and every claim of a patent. Moreover, while the PTO in its discretion may review claims for which *inter partes* review was not requested, nothing in the statute compels it to do so. To ensure that the PTO considers a claim for *inter partes* review, § 311(b)(2) requires that the party seeking reexamination demonstrate why the PTO should reexamine each and every claim for which it seeks review. Here, it is undisputed that Sony did not seek review of every claim under the '213 and '333 patents. Accordingly, Sony cannot now claim that the PTO wrongly failed to reexamine claims for which Sony never requested review, and its argument that AIPA compels a contrary result is unpersuasive.

(Slip copy at page 9.)

The *Sony* decision's reasoning and statutory interpretation apply analogously to *ex parte* reexamination, as the same relevant statutory language applies to both *inter partes* and *ex parte* reexamination. 35 U.S.C. § 302 provides that the *ex parte* reexamination "request must set forth the pertinency and manner of applying cited prior art to every claim for which reexamination is requested" (emphasis added), and 35 U.S.C. § 303 provides that "the Director will determine whether a substantial new question of patentability affecting any claim of the patent concerned is raised by the request..." (Emphasis added). These provisions are analogous to the language of 35 U.S.C. § 311(b)(2) and 35 U.S.C. § 312 applied and construed in *Sony*, and would be construed in the same manner. As the Director can decline to reexamine non-requested claims in an *inter partes* reexamination proceeding, the Director can likewise do so in *ex parte* reexamination proceeding. See *Notice of Clarification of Office Policy*

To Exercise Discretion in Reexamining Fewer Than All the Patent Claims (signed Oct. 5, 2006) 1311 OG 197 (Oct. 31, 2006). See also MPEP § 2240, Rev. 5, Aug. 2006.

Therefore, claims 2-4, 6-8, 10-14, 16-19, 23, 24, 29-31, 33-35, 37-41, 43-46, 50, 51, 54-56, 58-60, 62-66, 68-71, 75, 76, 81-83, 85-87, 89-93, 95-98, 102, 103, 108-110, 112-119, 121-124, 128 and 129 will not be reexamined in this ex *partes* reexamination proceeding.

Conclusion

Please mail any communications to:

Attn: Mail Stop "Ex Parte Reexam"
Central Reexamination Unit
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Please FAX any communications to:

(571) 273-9900
Central Reexamination Unit

Please hand-deliver any communications to:

Customer Service Window
Attn: Central Reexamination Unit
Randolph Building, Lobby Level
401 Dulaney Street
Alexandria, VA 22314

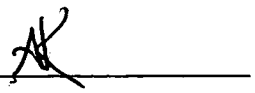
Any inquiry concerning this communication or earlier communications from the Examiner, or as to the status of this proceeding, should be directed to the Central Reexamination Unit at telephone number.(571) 272-7705.

Signed:

/Beverly M. Flanagan/

Beverly M. Flanagan
CRU Examiner
GAU 3993
(571) 272-4766

Conferee /JRJ/

Conferee 

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
90/011,466	01/31/2011	7792562	ADCI-GEN50	8367

68851 7590 02/25/2011

KNOBBE, MARTENS, OLSEN & BEAR, LLP
2040 MAIN STREET
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EXAMINER	
ART UNIT	PAPER NUMBER

DATE MAILED: 02/25/2011

Please find below and/or attached an Office communication concerning this application or proceeding.

UNITED STATES PATENT AND TRADEMARK OFFICE

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THIRD PARTY REQUESTER'S CORRESPONDENCE ADDRESS

Peter A. Socarras
BOZICEVIC FIELD & FRANCIS LLP
1900 University Ave., Suite 200
East Palo Alto, CA 94303

Date:
MAILED

FEB 25 2011

CENTRAL REEXAMINATION UNIT

EX PARTE REEXAMINATION COMMUNICATION TRANSMITTAL FORM

REEXAMINATION CONTROL NO. : 90011466
PATENT NO. : 7792562
ART UNIT : 3993

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified ex parte reexamination proceeding (37 CFR 1.550(f)).

Where this copy is supplied after the reply by requester, 37 CFR 1.535, or the time for filing a reply has passed, no submission on behalf of the ex parte reexamination requester will be acknowledged or considered (37 CFR 1.550(g)).

Ex Parte Reexamination Interview Summary – Pilot Program for Waiver of Patent Owner's Statement	Control No. 90/011,466	Patent For Which Reexamination is Requested 7,792,562
	Examiner Beverly Flanagan	Art Unit 3993

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address. --

All participants (USPTO official and patent owner):

(1) SHANETTE BROWN (3)

(2) ROSE THIESSEN (4)

Date of Telephonic Interview: 02/24/2011.

The USPTO official requested waiver of the patent owner's statement pursuant to the pilot program for waiver of patent owner's statement in *ex parte* reexamination proceedings.*

☒ The patent owner **agreed** to waive its right to file a patent owner's statement under 35 U.S.C. 304 in the event reexamination is ordered for the above-identified patent.

☐ The patent owner **did not agree** to waive its right to file a patent owner's statement under 35 U.S.C. 304 at this time.

The patent owner is not required to file a written statement of this telephone communication under 37 CFR 1.560(b) or otherwise. However, any disagreement as to this interview summary must be brought to the immediate attention of the USPTO, and no later than one month from the mailing date of this interview summary. Extensions of time are governed by 37 CFR 1.550(c).

*For more information regarding this pilot program, see *Pilot Program for Waiver of Patent Owner's Statement in Ex Parte Reexamination Proceedings*, 75 *Fed. Reg.* 47269 (August 5, 2010), available on the USPTO Web site at http://www.uspto.gov/patents/law/notices/2010.jsp.

☐ USPTO personnel were unable to reach the patent owner.

The patent owner may contact the USPTO personnel at the telephone number provided below if the patent owner decides to waive the right to file a patent owner's statement under 35 U.S.C. 304.

SHANETTE BROWN 571-272-6632

Signature and telephone number of the USPTO official who contacted or attempted to contact the patent owner.

cc: Requester (if third party requester)

UNITED STATES PATENT AND TRADEMARK OFFICE

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REEXAM CONTROL NUMBER	FILING OR 371 (c) DATE	PATENT NUMBER
90/011,466	01/31/2011	7792562

CONFIRMATION NO. 8367

REEXAMINATION REQUEST NOTICE

Peter A. Socarras
BOZICEVIC, FIELD & FRACIS LLP
1900 University Ave., Suite 200
East Palo Alto, CA 94303

OC000000045923650

Date Mailed: 02/10/2011

NOTICE OF REEXAMINATION REQUEST FILING DATE

(Third Party Requester)

Requester is hereby notified that the filing date of the request for reexamination is 01/31/2011, the date that the filing requirements of 37 CFR § 1.510 were received.

A decision on the request for reexamination will be mailed within three months from the filing date of the request for reexamination. (See 37 CFR 1.515(a)).

A copy of the Notice is being sent to the person identified by the requester as the patent owner. Further patent owner correspondence will be the latest attorney or agent of record in the patent file. (See 37 CFR 1.33). Any paper filed should include a reference to the present request for reexamination (by Reexamination Control Number).

cc: Patent Owner
68851
KNOBBE, MARTENS, OLSEN & BEAR, LLP
2040 MAIN STREET
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IRVINE, CA 92614

/jcmcdougald/

Legal Instruments Examiner
Central Reexamination Unit 571-272-7705; FAX No. 571-273-9900

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REEXAM CONTROL NUMBER	FILING OR 371 (c) DATE	PATENT NUMBER
90/011,466	01/31/2011	7792562

CONFIRMATION NO. 8367

REEXAM ASSIGNMENT NOTICE

68851
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IRVINE, CA 92614

OC000000045923651

Date Mailed: 02/10/2011

NOTICE OF ASSIGNMENT OF REEXAMINATION REQUEST

The above-identified request for reexamination has been assigned to Art Unit 3993. All future correspondence to the proceeding should be identified by the control number listed above and directed to the assigned Art Unit.

A copy of this Notice is being sent to the latest attorney or agent of record in the patent file or to all owners of record. (See 37 CFR 1.33(c)). If the addressee is not, or does not represent, the current owner, he or she is required to forward all communications regarding this proceeding to the current owner(s). An attorney or agent receiving this communication who does not represent the current owner(s) may wish to seek to withdraw pursuant to 37 CFR 1.36 in order to avoid receiving future communications. If the address of the current owner(s) is unknown, this communication should be returned within the request to withdraw pursuant to Section 1.36.

cc: Third Party Requester(if any)
Peter A. Socarras
BOZICEVIC, FIELD & FRACIS LLP
1900 University Ave., Suite 200
East Palo Alto, CA 94303

/jcmcdougald/

Legal Instruments Examiner
Central Reexamination Unit 571-272-7705; FAX No. 571-273-9900

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of: Shults et al.	Attorney Docket No. ADCI-GEN50
U.S. Patent No.: 7,792,562 (*issued from Appl. No. 12/645,097*)	Group Art Unit: *Not yet assigned*
Issued: September 7, 2010	Confirmation No. *Not yet assigned*
For: Device and Method For Determining Analyte Levels	Examiner: *Not yet assigned*
	Reexamination Control No.: *Not yet assigned*

ABBOTT DIABETES CARE INC.'S
REQUEST FOR *EX PARTE* REEXAMINATION
OF U.S. PATENT NO. 7,792,562
UNDER 35 U.S.C. § 302 AND 37 C.F.R. § 1.510

Mail Stop *Ex Parte* Reexam
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Abbott Diabetes Care Inc. (hereinafter "Requestor") requests reexamination under 35 U.S.C. § 302 and 37 C.F.R. § 1.510 of U.S. Patent No. 7,792,562, which issued on September 7, 2010, to Shults et al. (hereinafter "the Shults '562 patent").

As is fully explained and supported below, a substantial new question of patentability is raised by prior art teachings that were not considered or applied by the examiner during the original prosecution of the Shults '562 patent. More specifically, as outlined in Section V, a substantial new question of patentability is raised by teachings in each of the Kusano publication, the Allen '063 patent, the Mastrototaro publication, the Moatti-Sirat publication, and the Csöregi publication. Each of the Kusano publication, the Allen '063 patent, the Mastrototaro publication, the Moatti-Sirat publication, and the Csöregi publication, alone or in combination, teach the alleged patentable feature of the claims for which reexamination is requested. As such, a reasonable examiner would have considered the Kusano publication, the Allen '063 patent the

Mastrototaro publication, the Moatti-Sirat publication, and the Csöregi publication important in deciding whether said claims are patentable.

Pursuant to 37 C.F.R. § 1.510, included with this request for *ex parte* reexamination are the following:

- a citation of the patent and printed publication presented to provide substantial new questions of patentability (37 C.F.R. § 1.501);
- the fee for requesting *ex parte* reexamination as set forth in 37 C.F.R. § 1.20(c)(1) (paid via EFS Fee Payment Screen) (37 C.F.R. § 1.510(a));
- a statement pointing out each substantial new question of patentability based on the cited patent and printed publication (37 C.F.R. § 1.510(b)(1));
- an identification of every claim for which reexamination is requested, and a detailed explanation of the pertinence and manner of applying the patent and printed publication to every claim for which reexamination is requested (37 C.F.R. § 1.510(b)(2));
- a copy of each patent and printed publication relied upon or referred to in this request (37 C.F.R. § 1.510(b)(3));
- a copy of the entire patent (in double column format) for which reexamination is requested, and a copy of any disclaimer, certificate of correction, or reexamination certificate issued in the patent (37 C.F.R. § 1.510(b)(4));
- a certification that this request has been served in its entirety on the patent owner through the attorney of record during prosecution (37 C.F.R. § 1.510(b)(5)); and
- a statement that the attorney filing this request has the authority to act on behalf of the Requestor pursuant to 37 C.F.R. § 1.34 (37 C.F.R. § 1.510(f)).

TABLE OF CONTENTS

I. IDENTIFICATION OF CLAIMS FOR WHICH REEXAMINATION IS REQUESTED (37 C.F.R. § 1.510(b)(2))

Ex parte reexamination is requested of claims 1, 5, 9, 15, 20-22, 25-28, 32, 36, 42, 47-49, 52, 53, 57, 61, 67, 72-74, 77-80, 84, 88, 94, 99-101, 104-107, 111, 120, 125-127, and 130-132 of the Shults '562 patent (herein referred to individually and/or collectively as "the claims for which reexamination is requested"). In accordance with 37 C.F.R. § 1.510(b)(4), a copy of the Shults '562 patent is attached as **Exhibit A**.

II. CITATION OF PRIOR ART (37 C.F.R. § 1.501)

Reexamination is requested in view of the following documents, which are listed on the accompanying Form PTO/SB/08A. In accordance with 37 C.F.R. § 1.510(b)(3), a copy of each of the following references is attached.

Exhibit	Prior Art Document	Previously Cited?	Applied By The Examiner During Prosecution
B	U.S. Patent No. 5,322,063 (herein referred to as "the Allen '063 patent").	**Yes**	**No**
C	Kusano, H., Glucose enzyme electrode with percutaneous interface which operates independently of dissolved oxygen, *Clin. Phys. Physiol. Meas.*, vol. 10, 1:1-9 (1989) (herein referred to as "the Kusano publication").	**No**	**No**
D	Mastrototaro *et al.*, "An electroenzymatic glucose sensor fabricated on a flexible substrate," *Sensors and Actuators B*, 5:139-44 (1991) (herein referred to as "the Mastrototaro publication").	**Yes**	**No**
E	Moatti-Sirat *et al.*, Towards continuous glucose monitoring: in vivo evaluation of a miniaturized glucose sensor implanted for several days in rat subcutaneous tissue, *Diabetologia*, 35:224-230 (1992) (herein referred to as "the Moatti-Sirat publication").	**Yes**	**No**

F	Clarke *et al.*, Evaluating Clinical Accuracy of Systems for Self-Monitoring of Blood Glucose, *Diabetes Care*, Vol. 10, No. 5:622-628 (1987) (herein referred to as "the Clarke publication").	**No**	**No**
G	Csöregi *et al.*, Design, Characterization, and One-Point in Vivo Calibration of a Subcutaneously Implanted Glucose Electrode, *Analytical Chemistry*, 66(19):3131-3138 (October 1, 1994) (herein referred to as "the Csöregi publication").	**Yes**	**No**

The Allen '063 patent issued on June 21, 1994, which is more than one year before the effective filing date of the Shults '562 patent. As such, the Allen '063 patent qualifies as prior art against the Shults '562 patent under 35 U.S.C. § 102(b). A detailed explanation of how the Allen '063 patent presents a substantial new question of patentability, and of the pertinence and manner of applying the Allen '063 patent to the claims for which reexamination is requested is provided below.

The Kusano publication published in 1989, which is more than one year before the effective filing date of the Shults '562 patent. As such, the Kusano publication qualifies as prior art under 35 U.S.C. § 102(b). A detailed explanation of how the Kusano publication presents a substantial new question of patentability, and of the pertinence and manner of applying the Kusano publication to the claims for which reexamination is requested, is provided below.

The Mastrototaro publication published in 1991, which is more than one year before the effective filing date of the Shults '562 patent. As such, the Mastrototaro publication qualifies as prior art under 35 U.S.C. § 102(b). A detailed explanation of how the Mastrototaro publication presents a substantial new question of patentability, and of the pertinence and manner of applying the Mastrototaro publication to the claims for which reexamination is requested is provided below.

The Moatti-Sirat publication published in March of 1992, which is more than one year before the effective filing date of the Shults '562 patent. As such, the Moatti-Sirat publication qualifies as prior art under 35 U.S.C. § 102(b). A detailed explanation of how the Moatti-Sirat publication presents a substantial new question of patentability, and of the pertinence and manner

of applying the Moatti-Sirat publication to the claims for which reexamination is requested is provided below.

The Clarke publication published in September of 1987, which is more than one year before the effective filing date of the Shults '562 patent. As such, the Clarke publication qualifies as prior art under 35 U.S.C. § 102(b). A detailed explanation of the pertinence and manner of applying Clarke publication to the claims for which reexamination is requested is provided below.

The Csöregi publication published on October 1, 1994, which is more than one year before the effective filing date of the Shults '562 patent. As such, the Csöregi publication qualifies as prior art under 35 U.S.C. § 102(b). A detailed explanation of how the Csöregi publication presents a substantial new question of patentability, and of the pertinence and manner of applying the Csöregi publication to the claims for which reexamination is requested is provided below.

III. OVERVIEW OF APPLICABLE PATENT LAW

A. Substantial New Question of Patentability

In determining whether a substantial new question of patentability (SNQ) exists, M.P.E.P. § 2242, Subtitle I, paragraph 3, provides:

> A prior art patent or printed publication raises a substantial new question of patentability where there is a substantial likelihood that a reasonable examiner would consider the prior art or printed publication important in deciding whether or not the claim is patentable.

The Federal Circuit has held that "the existence of a substantial new question of patentability is not precluded by the fact that a patent or printed publication was previously cited by or to the Office or considered by the Office." *In re Swanson*, 540 F.3d 1368,1379-1380 (Fed. Cir. 2008). Thus, "a reference may present a substantial new question even if the examiner considered or cited a reference for one purpose in earlier proceedings." *Id.* The M.P.E.P. is consistent with the *Swanson* decision. M.P.E.P. § 2258.01(A) provides that "[f]or a reexamination that was ordered on or after November 2, 2002 ... reliance solely on old art (as the basis for a rejection) does not necessarily preclude the existence of a substantial new question of patentability that is based exclusively on that old art." Thus, "a SNQ may be based solely on old art where the old art is being presented/viewed in a new light, or in a different way, as compared with its use in the earlier concluded examination(s)." *Id.*

B. Broadest Reasonable Construction

For purposes of this reexamination request, each term of the claims is to be given its "broadest reasonable construction" consistent with the specification. M.P.E.P. § 2111; *In re Trans Texas Holding Corp.*, 498 F.3d 1290, 1298 (Fed. Cir. 2007). As the Federal Circuit noted in *Trans Texas*, the USPTO has traditionally applied this standard during reexamination and does not interpret claims as a court would interpret claims. Rather:

> [T]he PTO applies to verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in applicant's specification.

In re Morris, 127 F.3d 1048, 1054-55 (Fed. Cir. 1997).

The rationale underlying the "broadest reasonable construction" standard is that it reduces the possibility that a claim, after issuance or certificate of reexamination, will be interpreted more broadly than is justified. 37 C.F.R. § 1.555(b); M.P.E.P. § 2111.

C. Overview of Anticipation

A patent is unpatentable under 35 U.S.C. § 102 if it is anticipated by a prior art reference. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). A feature may be inherent if "the prior art necessarily functions in accordance with, or includes, the limitations." *Telemac Cellular Corp. v. Top Telecom, Inc.*, 247 F.3d 1316, 1328 (Fed. Cir. 2001). While normally only one reference should be used in making a rejection under 35 U.S.C. § 102, multiple references may be used when an extra reference is cited to show that a characteristic, which may not be disclosed in the main reference, is inherent. M.P.E.P. § 2131.01. The critical date of the extra reference, which is being used solely to show a universal fact, need not antedate the filing date of the application in question. *Id.*

D. Overview of Obviousness

Section 103 forbids issuance of a patent when "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a). In making an obviousness determination, "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions." *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007). In *KSR*, the Supreme Court rejected the "rigid approach" of the former "teaching-suggestion-motivation to combine" or "TSM" test. *Id.* at 1739. At the same time, the Court reaffirmed the principles of obviousness set forth in *Graham v. John Deere Co.*, 383 U.S. 1 (1966). *Id.* at 1734.

The obviousness analysis involves the comparison of the broadly construed claim to the prior art. In comparing the claim to the prior art, three factual inquiries must be addressed: (1)

the scope and content of the prior art must be ascertained; (2) the differences between the claimed invention and the prior art must be determined; and (3) the level of ordinary skill in the pertinent art at the time the invention was made must be evaluated. *Graham*, 383 U.S. at 17-18. As stated by the Supreme Court in *KSR*, "[w]hile the sequence of these questions might be reordered in any particular case, the [*Graham*] factors continue to define the inquiry that controls." *KSR*, 127 S.Ct. at 1734.

In view of the Supreme Court's decision in *KSR*, the Office issued "Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in View of the Supreme Court Decision in *KSR International Co. v. Teleflex Inc.*" See 72 Fed. Reg. 57,526 (Oct. 10, 2007) (hereinafter "Examination Guidelines"). According to the Examination Guidelines, "the Supreme Court particularly emphasized 'the need for caution in granting a patent based on the combination of elements found in the prior art.'" 72 Fed. Reg. at 57,526 (citing to *KSR*). The guidelines further state that "the focus when making a determination of obviousness should be on what a person of ordinary skill in the pertinent art would have known at the time of the invention, and on what such a person would have reasonably expected to have been able to do in view of that knowledge." 72 Fed. Reg. at 57,527. According to the Supreme Court, the "person of ordinary skill" should be viewed as "a person of ordinary creativity, not an automaton." *KSR*, 127 S.Ct. at 1742. The Supreme Court further stated that "in many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle." *Id.*

Further, "[w]here a claimed range overlaps with a range disclosed in the prior art, there is a presumption of obviousness." *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1311 (Fed. Cir. 2006) (citations omitted); see also M.P.E.P. § 2144.05.

IV. OVERVIEW OF THE SHULTS '562 PATENT

A. The Shults '562 patent

The Shults '562 patent issued on September 7, 2010, from U.S. Patent Application No. 12/645,097 ("the Shults '097 application"). The Shults '097 application was filed on December 22, 2009, and claims priority as a continuation application to U.S. Patent Application No. 09/447,227, filed on November 22, 1999, which is a divisional of U.S. Patent Application No. 08/811,473, filed on March 4, 1997.

The Shults '562 patent relates to devices for monitoring glucose levels in a biological fluid. See the Shults '562 patent, col. 1, lns. 10-14. More specifically, the Shults '562 patent describes a device for measuring glucose concentration having an analyte sensing mechanism and a membrane disposed on a portion of the sensing mechanism. See claim 1, col. 24, lns. 15-21. The Shults '562 patent claims a device that "is capable of exhibiting, at a glucose concentration of 400 mg/dL, no more than a 10% drop in sensor output over a range of pO_2 from 150 mm Hg down to 30 mm Hg." See claim 1, col. 24, lns. 23-25; and Example 6, col. 21, lns. 21-41.

As will be outlined below, the claimed sensor output criteria played an essential role in the examiner's decision to allow the claims for which reexamination is requested. The examiner specifically emphasized in the reasons for allowance of the claims that the claims were allowed because the examiner did not identify any art that described the sensor output criteria of "exhibiting, at a glucose concentration of 400 mg/dL, no more than a 10% drop in sensor output over a range of pO_2 from 150 mm Hg down to 30 mm Hg."

B. Relevant Prosecution History of the Shults '562 patent

The Shults '097 application was filed with 23 original claims. Original application claim 1 read as follows:

> 1. A device for measuring a glucose concentration in a host, the device comprising:
>
> a sensing mechanism operably connected to an electronic circuit and configured to continuously measure a signal associated with a glucose concentration in a host for a period of time; and

> a membrane located over at least a portion of the sensing mechanism, wherein the membrane is configured to control a flux of oxygen and glucose;
>
> wherein the device is capable of exhibiting, at a glucose concentration of about 400 mg/dL, no more than a 10% drop in sensor output over a range of pO_2 from about 150 mm Hg down to about 30 mm Hg.

On March 1, 2010, applicants added claim 24 in a Preliminary Amendment.

On May 7, 2010, applicants filed a Terminal Disclaimer over U.S. Patent Application No. 09/447,227.

On May 14, 2010, applicants amended claims 1-3, 5-10, and 12-16, and added claims 24-132 in a Preliminary Amendment.[1] Claim 1 was amended as follows:

> 1. A device for measuring a glucose concentration in a host, the device comprising:
>
> a ~~sensing mechanism~~ sensor operably connected to an electronic circuit and configured to continuously measure a signal ~~associated with~~ indicative of a glucose concentration in a host for a period of time; and
>
> a membrane located over at least a portion of the sensor ~~sensing mechanism~~, wherein the membrane is configured to control a flux of oxygen and glucose;
>
> wherein the device is capable of exhibiting, at a glucose concentration of about 400 mg/dL, no more than a 10% drop in sensor output over a range of pO_2 from about 150 mm Hg down to about 30 mm Hg, and wherein the device is configured to use an *in vitro* calibration factor for initial calibration.

On June 4, 2010, the examiner conducted a telephone interview with applicants' representative. An interview summary was not issued. However, applicants' representative did provide authorization for an examiner amendment, as provided in the Notice of Allowance.

On June 28, 2010, the examiner issued a Notice of Allowance. In the Notice of Allowability, the examiner provided amendments to claims 1, 13-15, 17, 18, 20-23, 27, 28, 40-42, 44-45, 47-50, 53, 65-67, 69-75, 79, 80, 92-94, 96, 97, 99-1 02, 106, 107, 1 18-1 20, 122, 123, 125-1 28, and 132. Claim 1 was amended as follows:

[1] The claim 24 added on March 1, 2010, did not appear on the Preliminary Amendment of May 14, 2010.

> 1. A device for measuring a glucose concentration in a host, the device comprising:
>
> a sensor operably connected to an electronic circuit and configured to continuously measure a signal indicative of a glucose concentration in a host for a period of time; and
>
> a membrane located over at least a portion of the sensor, ~~wherein~~ the membrane [[is]] comprising a layer configured to control a flux of oxygen and glucose;
>
> wherein the device is capable of exhibiting, at a glucose concentration of about 400 mg/dL, no more than a 10% drop in sensor output over a range of pO_2 from [[about]] 150 mm Hg down to [[about]] 30 mm Hg, and wherein the device is configured to use an *in vitro* calibration factor for initial calibration.

The examiner provided reasons for the examiner amendment. Specifically, the examiner stated:

> Claims 1, 28, 53, 80, 107 were amended to remove the words about, as the support in the specification was only for 30-150 mm hg exactly and to recite that the membrane has a layer .. at applicant's request.
>
> Claims 13, 14, 40, 41, 65, 66, 92, 93, 118, and 119 were amended to correspond to the amended base claim and refer to "the layer', [sic] as now claimed.
>
> Claims 15, 42, 67, 94, and 120 were amended to better correspond to the specification.
>
> Claims 17, 18, 44, 45, 69, 70, 96, 97, 112, and 123 were amended in that there was only support for the resistance layer (layer to control flux …) having the claimed thickness, not the whole membrane.
>
> Claims 20-22, 47-49, 72-74, 99-101, and 125-127 were amended in that the specification has support on page 33 for the useful life to be from day 22 to 60, so it was at least each of the recited days, as rewritten.
>
> Claims 23, 50, 75, 102, and 128 were amended at applicant's request.
>
> Claims 27, 79, 106, and 132 were amended to remove the words about, as the support in the specification was only up to 400 mg/dl.

Notice of Allowability, dated June 28, 2010, pg. 8-9.

It does not appear that any of the amendments were presented to overcome any cited prior art. On page 10 of the Notice of Allowability, the examiner stated:

> Third, the examiner and ms. Johnson [sic] discussed the Zhang et al article entitled "In vitro and in vivo evaluation of oxygen effects . . ." cited by applicant on 5/6/2010. Figure 3 and the associated discussion show the variation in sensor output as glucose concentration increases. The claimed data point was at 400 mg/dl, which corresponds to 22 mM. This data point is not shown in figure 3. The article does state that sensor B was linear to 30mM and that at 15 mM, the variation in sensor output from 7.6-150 mm hg was 5%. However, there is not enough information provided to determine what the change would be at 22 mM. Therefore, the claims define over this article.

Further, on page 11 of the Notice of Allowability, the examiner provided the following reasons for allowance:

> Claims 1-132 are allowable in that none of the art has a sensor that meets the 10% drop in sensor output criteria, as defined in the claims.

On September 7, 2010, the Shults '097 application issued as the Shults '562 patent.

C. Issued Claims of the Shults '562 patent

The Shults '562 patent issued with five independent claims, and 132 total claims. The claims for which reexamination is requested are reproduced below. Emphasis has been added to the patentable feature, as determined by the Examiner, of each independent claim.

> 1. A device for measuring a glucose concentration in a host, the device comprising:
>
> a sensor operably connected to an electronic circuit and configured to continuously measure a signal indicative of a glucose concentration in a host for a period of time; and
>
> a membrane located over at least a portion of the sensor, the membrane comprising a layer configured to control a flux of oxygen and glucose;
>
> wherein the device is capable of exhibiting, at a glucose concentration of 400 mg/dL, ***no more than a 10% drop in sensor output*** over a range of pO_2 from 150 mm Hg down to 30 mm Hg, and wherein the device is configured to use an in vitro calibration factor for initial calibration.
>
> 5. The device of claim 1, wherein the membrane comprises a layer comprising an enzyme.

9. The device of claim 1, wherein the membrane comprises a urethane polymer or a polyurethane.

15. The device of claim 1, wherein at least 95% of glucose concentration values measured by the device are within 25% of corresponding values determined by analysis of blood over the period of time.

20. The device of claim 1, wherein the period of time is at least about 3 days.

21. The device of claim 1, wherein the period of time is at least about 5 days.

22. The device of claim 1, wherein the period of time is at least about 7 days.

25. The device of claim 1, wherein the device is configured for single-point recalibration.

26. The device of claim 1, wherein the device is configured to be implanted in the host.

27. The device of claim 1, wherein the device is configured to respond substantially linearly to changes in glucose concentration at a glucose concentration of up to at least 400 mg/dL.

28. A device for measuring a glucose concentration in a host, the device comprising:

an electrode surface operably connected to an electronic circuit and configured to continuously measure a signal indicative of a glucose concentration in a host for a period of time; and

a membrane located over at least a portion of the electrode surface, the membrane comprising a layer configured to control a flux of oxygen and glucose;

wherein the device is capable of exhibiting, at a glucose concentration of 400 mg/dL, ***no more than a 10% drop in sensor output*** over a range of pO_2 from 150 mm Hg down to 30 mm Hg; and wherein the device is configured to be implanted in the host.

32. The device of claim 28, wherein the membrane comprises a layer comprising an enzyme.

36. The device of claim 28, wherein the membrane comprises a urethane polymer or a polyurethane.

42. The device of claim 28, wherein at least 95% of glucose concentration values measured by the device are within 25% of corresponding values determined by analysis of blood over the period of time.

47. The device of claim 28, wherein the period of time is at least about 3 days.

48. The device of claim 28, wherein the period of time is at least about 5 days.

49. The device of claim 28, wherein the period of time is at least about 7 days.

52. The device of claim 28, wherein the device is configured for single-point recalibration.

53. A device for measuring a glucose concentration in a host, the device comprising:

a sensor operably connected to an electronic circuit and configured to continuously measure a signal indicative of a glucose concentration in a host for a period of time; and

a membrane located over at least a portion of the sensor, the membrane comprising a layer configured to control a flux of oxygen and glucose;

wherein the device is capable of exhibiting, at a glucose concentration of 400 mg/dL, ***no more than a 10% drop in sensor output*** over a range of pO_2 from 150 mm Hg down to 30 mm Hg; and wherein the device is configured to respond substantially linearly to changes in glucose concentration at a glucose concentration of up to at least 400 mg/dL.

57. The device of claim 53, wherein the membrane comprises a layer comprising an enzyme.

61. The device of claim 53, wherein the membrane comprises a urethane polymer or a polyurethane.

67. The device of claim 53, wherein at least 95% of glucose concentration values measured by the device are within 25% of corresponding values determined by analysis of blood over the period of time.

72. The device of claim 53, wherein the period of time is at least about 3 days.

73. The device of claim 53, wherein the period of time is at least about 5 days.

74. The device of claim 53, wherein the period of time is at least about 7 days.

77. The device of claim 53, wherein the device is configured for single-point recalibration.

78. The device of claim 53, wherein the device is configured to be implanted in the host.

79. The device of claim 53, wherein the device is configured to respond substantially linearly to changes in glucose concentration at a glucose concentration of up to at least 400 mg/dL.

80. A device for measuring a glucose concentration in a host, the device comprising:

a sensor operably connected to an electronic circuit and configured to continuously measure a signal indicative of a glucose concentration in a host for a period of time; and

a membrane located over at least a portion of the sensor, the membrane comprising a layer configured to control a flux of oxygen and glucose;

wherein the device is capable of exhibiting, at a glucose concentration of 400 mg/dL, ***no more than a 10% drop in sensor output*** over a range of pO_2 from 150 mm Hg down to 30 mm Hg; and wherein the device is capable of attaining a 90% time response to a 100 mg/dL glucose concentration step in less than 5 minutes.

84. The device of claim 80, wherein the membrane comprises a layer comprising an enzyme.

88. The device of claim 80, wherein the membrane comprises a urethane polymer or a polyurethane.

94. The device of claim 80, wherein at least 95% of glucose concentration values measured by the device are within 25% of corresponding values determined by analysis of blood over the period of time.

99. The device of claim 80, wherein the period of time is at least about 3 days.

100. The device of claim 80, wherein the period of time is at

least about 5 days.

101. The device of claim 80, wherein the period of time is at least about 7 days.

104. The device of claim 80, wherein the device is configured for single-point recalibration.

105. The device of claim 80, wherein the device is configured to be implanted in the host.

106. The device of claim 80, wherein the device is configured to respond substantially linearly to changes in glucose concentration at a glucose concentration of up to at least 400 mg/dL.

107. A device for measuring a glucose concentration in a host, the device comprising:

a sensor operably connected to an electronic circuit and configured to continuously measure a signal indicative of a glucose concentration in a host for a period of time; and

a membrane located over at least a portion of the sensor, wherein the membrane comprises a layer configured to control a flux of oxygen and glucose,

wherein the layer comprises a polyurethane or urethane polymer; wherein the device is capable of exhibiting, at a glucose concentration of 400 mg/dL, ***no more than a 10% drop in sensor output*** over a range of pO_2 from 150 mm Hg down to 30 mm Hg.

111. The device of claim 107, wherein the membrane comprises a layer comprising an enzyme.

120. The device of claim 107, wherein at least 95% of glucose concentration values measured by the device are within 25% of corresponding values determined by analysis of blood over the period of time.

125. The device of claim 107, wherein the period of time is at least about 3 days.

126. The device of claim 107, wherein the period of time is at least about 5 days.

127. The device of claim 107, wherein the period of time is at least about 7 days.

130. The device of claim 107, wherein the device is configured

for single-point recalibration.

131. The device of claim 107, wherein the device is configured to be implanted in the host.

132. The device of claim 107, wherein the device is configured to respond substantially linearly to changes in glucose concentration at a glucose concentration of up to at least 400 mg/dL.

V. STATEMENT POINTING OUT EACH SUBSTANTIAL NEW QUESTION OF PATENTABILITY (37 C.F.R. § 1.510(b)(1))

A. The Allen '063 patent raises an SNQ because the Allen '063 patent teaches a sensing device that meets the claimed sensor output criteria.

The Allen '063 patent was cited during prosecution of the Shults '562 patent, but the teachings of the Allen '063 patent were not applied against the claims of the Shults '562 patent. The Allen '063 patent teaches a device exhibiting, at a glucose concentration of 400 mg/dL, no more than a 10% drop in sensor output over a range of pO_2 from 150 mmHg down to 30 mmHg, as called for in the claims for which reexamination is requested. There is no indication that the examiner found, considered, or applied any prior art reference that taught such limitation. In fact, the examiner explicitly stated that claims 1-132 were allowable because the examiner did not identify any art showing "a sensor that meets the 10% drop in sensor output criteria, as defined in the claims." As such, a reasonable examiner would consider the teachings of the Allen '063 patent important in deciding whether the claims for which reexamination is requested are patentable.

The Allen '063 patent is directed to the same problem as the Shults '562 patent. Namely, the Allen '063 patent is directed to the development of a device for measuring glucose concentration in a host. See the Allen '063 patent, Abstract. The Allen '063 patent presents a sensor system that measures glucose concentrations from 0 to 400 mg/dL, in a fluid with an oxygen concentration of ranging from 7 mmHg to 150 mmHg. See the Allen '063 patent, col. 9, lns. 50-68. As such, the ranges disclosed in the Allen '063 patent encompass the ranges claimed in the Shults '562 patent.

The Allen '063 patent further states:

> A computer-controlled system was built to automatically expose sixteen sensors provided with membranes of the invention simultaneously to an array of ***four different glucose concentrations: 0, 100, 200, and 400 mg/dL and four different oxygen concentrations: 1, 2, 5, and 20.9% oxygen (approximately 7-150 mmHg).***
>
> Using this system, it was found that the sensors encapsulated in the membrane ***responded linearly to glucose concentrations ranging from 0-400 mg/dL*** (correlation coefficient >0.98) and had a very reproducible baseline value in a buffer solution with no glucose.

> This characteristic of the sensor allowed a one-point calibration to be adequate. In addition, ***varying the oxygen concentration of the calibration solution between 1 and 20.9% had no effect on the output of the sensor, even at high glucose concentrations. The resolution was better than 10% throughout the entire calibration range*** and the 90% response time for a change in the glucose concentration from 0 to 100 mg/dL was less than 90 seconds.

Id. (emphasis added).

There is no indication in the record that the examiner identified and applied any prior art references that taught a device exhibiting, at a glucose concentration of 400 mg/dL, no more than a 10% drop in sensor output over a range of pO_2 from 150 mmHg down to 30 mmHg, as called for in the claims for which reexamination is requested. As outlined above, such limitation is taught by the Allen '063 patent. As such, the Allen '063 patent raises a substantial new question of patentability because a reasonable examiner would consider the teachings of the Allen '063 patent important in deciding whether the claims for which reexamination is requested are patentable. See M.P.E.P. § 2242, Subtitle I, paragraph 3.

A detailed explanation of the pertinence and manner of applying the teachings of the Allen '063 patent to the claims for which reexamination is requested is provided below in Section VI.

B. The Kusano publication raises an SNQ because the Kusano publication teaches a sensing device that meets the claimed sensor output criteria.

The Kusano publication was not cited during prosecution of the Shults '562 patent. Further, the examiner did not identify or apply any prior art that taught a device with the features taught in the Kusano publication. More specifically, the Kusano publication teaches a device exhibiting, at a glucose concentration of 400 mg/dL, no more than a 10% drop in sensor output over a range of pO_2 from 150 mmHg down to 30 mmHg, as called for in the claims for which reexamination is requested. There is no indication that the examiner found, considered, or applied any prior art reference that taught such limitation. In fact, the examiner explicitly stated that claims 1-132 were allowable because the examiner did not identify any art showing "a sensor that meets the 10% drop in sensor output criteria, as defined in the claims." As such, a reasonable examiner would consider the teachings of the Kusano publication important in deciding whether the claims for which reexamination is requested are patentable.

The Kusano publication is directed to the same problem as the Shults '562 patent. Namely, the Kusano publication is directed to the development of a device for measuring glucose concentration in a host. See the Kusano publication, Abstract. The Kusano publication presents a sensor system that measures glucose concentrations from 0 to 500 mg/dL, in a fluid with an oxygen concentration ranging from 0 kPa (0 mmHg) to 20.5 kPa (154 mmHg). See the Kusano publication, pgs. 6-7, and Figure 8. As such, the ranges disclosed in the Kusano publication encompass the ranges claimed in the Shults '562 patent.

The Kusano publication further states:

> The electrode calibration curve is shown in figure 8. Reproducibility at a glucose concentration of 500 mg dl^{-1} (27.8 mmol l^{-1}) was within an error of ± 3%. ***Oxygen concentration had no effect on electrode response***.

The Kusano publication, pgs. 6-7 (emphasis added).

Figure 8 of the Kusano publication (reproduced below) shows a linear current measurement up to 500 mg/dL, and a negligible drop in sensor output (i.e., "an error of ± 3%") as the pO_2 is varied from 0 kPa (0 mmHg) to 20.5 kPa (154 mmHg).

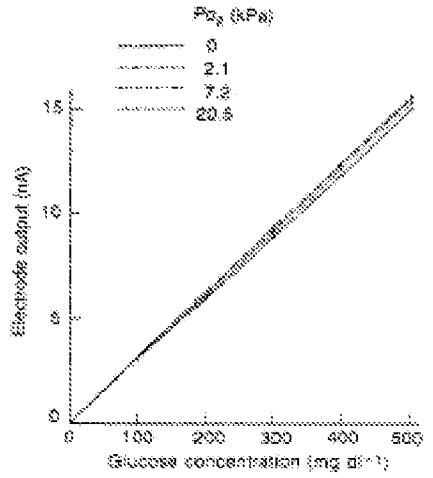

Figure 8. Electrode calibration curves under various Po_2.

The concluding remarks of the Kusano publication further state:

> Glucose concentrations of 0 to 500 mg dl^{-1} (27.8 mmol l^{-1}) could be measured without being affected by oxygen concentration in the range of 0 to 163 mmHg (21.7 kPa).

The Kusano publication, pg. 8.

There is no indication in the record that the examiner identified and applied any prior art references that taught a device exhibiting, at a glucose concentration of 400 mg/dL, no more than a 10% drop in sensor output over a range of pO_2 from 150 mmHg down to 30 mmHg, as called for in the claims for which reexamination is requested. As outlined above, such limitation is taught by the Kusano publication. As such, the Kusano publication raises a substantial new question of patentability because a reasonable examiner would consider the teachings of the Kusano publication important in deciding whether the claims for which reexamination is requested are patentable. See M.P.E.P. § 2242, Subtitle I, paragraph 3.

A detailed explanation of the pertinence and manner of applying the teachings of the Kusano publication to the claims for which reexamination is requested is provided below in Section VI.

VI. DETAILED EXPLANATION OF PERTINENCE AND MANNER OF APPLYING THE CITED PRIOR ART TO EVERY CLAIM FOR WHICH REEXAMINATION IS REQUESTED (37 C.F.R. § 1.510(b)(2))

A. Claims 1, 5, 9, 20, 26-28, 32, 36, 47, 53, 57, 61, 72, 78-80, 84, 88, 99, 105-107, 111, 125, 131, and 132 are anticipated under 35 U.S.C. § 102 by the Allen '063 patent.

Claims 1, 5, 9, 20, 26-28, 32, 36, 47, 53, 57, 61, 72, 78-80, 84, 88, 99, 105-107, 111, 125, 131, and 132 are anticipated under 35 U.S.C. § 102(b) by the Allen '063 patent. Sections VI.A.1 – VI.A.27 detail how each and every feature of claims 1, 5, 9, 20, 26-28, 32, 36, 47, 53, 57, 61, 72, 78-80, 84, 88, 99, 105-107, 111, 125, 131, and 132 are taught or suggested by the Allen '063 patent. For the examiner's convenience, the arguments presented herein are summarized in the table provided in **Exhibit H**.

1. Independent Claim 1

> Claim 1. A device for measuring a glucose concentration in a host, the device comprising:
>
> *Part of Claim 1*

The Allen '063 patent teaches a device for measuring glucose concentration in a host. See the Allen '063 patent, Abstract. Additionally, the Allen '063 patent incorporates by reference the Mastrototaro publication. See the Allen '063 patent, col. 9, lns. 23-29.

The Mastrototaro publication teaches a device for measuring glucose concentration in a host. See the Mastrototaro publication, Abstract; and pg. 143, Discussion.

> a sensor operably connected to an electronic circuit and configured to continuously measure a signal indicative of a glucose concentration in a host for a period of time; and
>
> *Part of Claim 1*

The Allen '063 patent teaches a sensor operably connected to an electronic circuit and configured to continuously measure a signal indicative of a glucose concentration in a host for a period of time. See the Allen '063 patent, col. 5, lns. 7-15.

The Mastrototaro publication, incorporated by reference into the Allen '063 patent, teaches a sensor operably connected to an electronic circuit and configured to continuously measure a signal indicative of a glucose concentration in a host for a period of time. See the Mastrototaro publication, pgs. 140-141.

> a membrane located over at least a portion of the sensor, the membrane comprising a layer configured to control a flux of oxygen and glucose;
>
> *Part of Claim 1*

The Allen '063 patent teaches a membrane located over at least a portion of the sensor, the membrane comprising a layer configured to control a flux of oxygen and glucose. See the Allen '063 patent, col. 5, lns. 34-43.

The Mastrototaro publication teaches a membrane located over at least a portion of the sensor, the membrane comprising a layer configured to control a flux of oxygen and glucose. See the Mastrototaro publication, pg. 141, stating: "The entire sensor is covered with a differentially permeable biocompatible membrane. This proprietary member is two to three orders of magnitude more permeable to oxygen than glucose, thus compensating for the 'oxygen effect.'"

> wherein the device is capable of exhibiting, at a glucose concentration of 400 mg/dL, no more than a 10% drop in sensor output over a range of pO_2 from 150 mm Hg down to 30 mm Hg,
>
> *Part of Claim 1*

The Allen '063 patent teaches a device is capable of exhibiting, at a glucose concentration of 400 mg/dL, no more than a 10% drop in sensor output over a range of pO_2 from 150 mmHg down to 30 mmHg. See the Allen '063 patent, col. 9, lns. 50-68.

Specifically, the Allen '063 patent teaches a sensor system that measures glucose concentrations from 0 to 400 mg/dL, in a fluid with an oxygen concentration ranging from 7 mmHg to 150 mmHg. See the Allen '063 patent, col. 9, lns. 50-68. As such, the ranges disclosed in the Allen '063 patent encompass the ranges claimed in the Shults '562 patent.

The Allen '063 patent further states:

> A computer-controlled system was built to automatically expose sixteen sensors provided with membranes of the invention simultaneously to an array of ***four different glucose concentrations: 0, 100, 200, and 400 mg/dL and four different oxygen concentrations: 1, 2, 5, and 20.9% oxygen (approximately 7-150 mmHg).***
>
> Using this system, it was found that the sensors encapsulated in the membrane ***responded linearly to glucose concentrations ranging***

> ***from 0-400 mg/dL*** (correlation coefficient >0.98) and had a very reproducible baseline value in a buffer solution with no glucose. This characteristic of the sensor allowed a one-point calibration to be adequate. In addition, ***varying the oxygen concentration of the calibration solution between 1 and 20.9% had no effect on the output of the sensor, even at high glucose concentrations. The resolution was better than 10% throughout the entire calibration range*** and the 90% response time for a change in the glucose concentration from 0 to 100 mg/dL was less than 90 seconds.

Id. (emphasis added).

> and wherein the device is configured to use an in vitro calibration factor for initial calibration.
>
> *Part of Claim 1*

On page 141, the Mastrototaro publication states:

> The sensors have been shown to respond linearly ($R^2 > 0.98$) to glucose concentrations ranging from 0 to 400 mg/dl (Fig. 1). The linearity of response is important because it indicates that a two-point sensor calibration is sufficient. Furthermore, since the sensors have a predetermined and reproducible baseline value, a one-point calibration is possible.

In its concluding remarks, the Mastrototaro publication further states: "Finally, it is important to correlate an *in vitro* calibration of the sensors prior to implantation to *in vivo* response." The Mastrototaro publication, pg. 143, Discussion.

2. Dependent Claim 5

In addition to showing each and every feature of claim 1, the Allen '063 patent discloses the features of claim 5, which depends from claim 1.

> Claim 5. The device of claim 1, wherein the membrane comprises a layer comprising an enzyme.

The membrane disclosed in the Allen '063 patent includes an enzyme layer of glucose oxidase (19). See the Allen '063 patent, col. 5, lns. 28-31; and FIG. 2. The Mastrototaro publication teaches a membrane comprising an enzyme layer. See the Mastrototaro publication, pg. 140.

3. Dependent Claim 9

In addition to showing each and every feature of claim 1, the Allen '063 patent discloses the features of claim 9, which depends from claim 1.

> Claim 9. The device of claim 1, wherein the membrane comprises a urethane polymer or a polyurethane.

The Allen '063 patent teaches forming the membrane of a polyurethane. See the Allen '063 patent, col. 5, lns. 44-45.

4. Dependent Claim 20

In addition to showing each and every feature of claim 1, the Allen '063 patent discloses the features of claim 20, which depends from claim 1.

> Claim 20. The device of claim 1, wherein the period of time is at least about 3 days.

The Allen '063 patent demonstrates that the sensor is able to function continuously for at least three days. See, for example, the Allen '063 patent, col. 10, lns. 3-9.

5. Dependent Claim 26

In addition to showing each and every feature of claim 1, the Allen '063 patent discloses the features of claim 26, which depends from claim 1.

> Claim 26. The device of claim 1, wherein the device is configured to be implanted in the host.

The Allen '063 patent teaches configuring the sensor to be implanted in the host. See the Allen '063 patent, col. 10, lns. 10-23.

6. Dependent Claim 27

In addition to showing each and every feature of claim 1, the Allen '063 patent discloses the features of claim 27, which depends from claim 1.

> Claim 27. The device of claim 1, wherein the device is configured to respond substantially linearly to changes in glucose concentration at a glucose concentration of up to at least 400 mg/dL.

The Allen '063 patent teaches the device is configured to respond substantially linearly to changes in glucose concentration at a glucose concentration of up to about 400 mg/dL. See, for example, the Allen '063 patent, col. 9, lns. 57-61.

7. Independent Claim 28

> Claim 28. A device for measuring a glucose concentration in a host, the device comprising:
>
> *Part of Claim 28*

The Allen '063 patent teaches a device for measuring glucose concentration in a host. See the Allen '063 patent, Abstract. The Allen '063 patent incorporates by reference the Mastrototaro publication. See the Allen '063 patent, col. 9, lns. 23-29.

The Mastrototaro publication teaches a device for measuring glucose concentration in a host. See the Mastrototaro publication, Abstract; and pg. 143, Discussion.

> an electrode surface operably connected to an electronic circuit and configured to continuously measure a signal indicative of a glucose concentration in a host for a period of time; and
>
> *Part of Claim 28*

The Allen '063 patent teaches an electrode surface operably connected to an electronic circuit and configured to continuously measure a signal indicative of a glucose concentration in a host for a period of time. See the Allen '063 patent, col. 5, lns. 7-15.

The Mastrototaro publication teaches an electrode surface operably connected to an electronic circuit and configured to continuously measure a signal indicative of a glucose concentration in a host for a period of time. See the Mastrototaro publication, pgs. 140-141.

> a membrane located over at least a portion of the electrode surface, the membrane comprising a layer configured to control a flux of oxygen and glucose;
>
> *Part of Claim 28*

The Allen '063 patent teaches a membrane located over at least a portion of the electrode surface, the membrane comprising a layer configured to control a flux of oxygen and glucose. See the Allen '063 patent, col. 5, lns. 34-43.

The Mastrototaro publication teaches a membrane located over at least a portion of the electrode surface, the membrane comprising a layer configured to control a flux of oxygen and glucose. See the Mastrototaro publication, pg. 141, stating: "The entire sensor is covered with a differentially permeable biocompatible membrane. This proprietary member is two to three orders of magnitude more permeable to oxygen than glucose, thus compensating for the 'oxygen effect.'"

> wherein the device is capable of exhibiting, at a glucose concentration of 400 mg/dL, no more than a 10% drop in sensor output over a range of pO_2 from 150 mm Hg down to 30 mm Hg;
>
> *Part of Claim 28*

The Allen '063 patent teaches a device is capable of exhibiting, at a glucose concentration of 400 mg/dL, no more than a 10% drop in sensor output over a range of pO_2 from 150 mmHg down to 30 mmHg. See the Allen '063 patent, col. 9, lns. 50-67.

Specifically, the Allen '063 patent presents a sensor system that measures glucose concentrations from 0 to 400 mg/dL, in a fluid with an oxygen concentration ranging from 7 mmHg to 150 mmHg. See the Allen '063 patent, col. 9, lns. 50-68. As such, the ranges disclosed in the Allen '063 patent encompass the ranges claimed in the Shults '562 patent.

The Allen '063 patent further states:

> A computer-controlled system was built to automatically expose sixteen sensors provided with membranes of the invention simultaneously to an array of ***four different glucose concentrations: 0, 100, 200, and 400 mg/dL and four different oxygen concentrations: 1, 2, 5, and 20.9% oxygen (approximately 7-150 mmHg).***
>
> Using this system, it was found that the sensors encapsulated in the membrane ***responded linearly to glucose concentrations ranging***

> ***from 0-400 mg/dL*** (correlation coefficient >0.98) and had a very reproducible baseline value in a buffer solution with no glucose. This characteristic of the sensor allowed a one-point calibration to be adequate. In addition, ***varying the oxygen concentration of the calibration solution between 1 and 20.9% had no effect on the output of the sensor, even at high glucose concentrations. The resolution was better than 10% throughout the entire calibration range*** and the 90% response time for a change in the glucose concentration from 0 to 100 mg/dL was less than 90 seconds.

Id. (emphasis added).

> and wherein the device is configured to be implanted in the host.
>
> *Part of Claim 28*

The Allen '063 patent teaches configuring the sensor to be implanted in the host. See the Allen '063 patent, col. 10, lns. 10-23.

8. Dependent Claim 32

In addition to showing each and every feature of claim 28, the Allen '063 patent discloses the features of claim 32, which depends from claim 28.

> Claim 32. The device of claim 28, wherein the membrane comprises a layer comprising an enzyme.

The membrane disclosed in the Allen '063 patent includes an enzyme layer of glucose oxidase (19). See the Allen '063 patent, col. 5, lns. 28-31; and FIG. 2. The Mastrototaro publication teaches a membrane comprising an enzyme layer. See the Mastrototaro publication, pg. 140.

9. Dependent Claim 36

In addition to showing each and every feature of claim 28, the Allen '063 patent discloses the features of claim 36, which depends from claim 28.

> Claim 36. The device of claim 28, wherein the membrane comprises a urethane polymer or a polyurethane.

The Allen '063 patent teaches forming the membrane of a polyurethane. See the Allen '063 patent, col. 5, lns. 44-45.

10. Dependent Claim 47

In addition to showing each and every feature of claim 28, the Allen '063 patent discloses the features of claim 47, which depends from claim 28.

> Claim 47. The device of claim 28, wherein the period of time is at least about 3 days.

The Allen '063 patent demonstrates that the sensor is able to function continuously for at least three days. See, for example, the Allen '063 patent, col. 10, lns. 3-9.

11. Independent Claim 53

> Claim 53. A device for measuring a glucose concentration in a host, the device comprising:
>
> *Part of Claim 53*

The Allen '063 patent teaches a device for measuring glucose concentration in a host. See the Allen '063 patent, Abstract. The Allen '063 patent incorporates by reference the Mastrototaro publication. See the Allen '063 patent, col. 9, lns. 23-29.

The Mastrototaro publication teaches a device for measuring glucose concentration in a host. See the Mastrototaro publication, Abstract; and pg. 143, Discussion.

> a sensor operably connected to an electronic circuit and configured to continuously measure a signal indicative of a glucose concentration in a host for a period of time; and
>
> *Part of Claim 53*

The Allen '063 patent teaches a sensor operably connected to an electronic circuit and configured to continuously measure a signal indicative of a glucose concentration in a host for a period of time. See the Allen '063 patent, col. 5, lns. 7-15.

The Mastrototaro publication teaches a sensor operably connected to an electronic circuit and configured to continuously measure a signal indicative of a glucose concentration in a host for a period of time. See the Mastrototaro publication, pgs. 140-141.

> a membrane located over at least a portion of the sensor, the membrane comprising a layer configured to control a flux of oxygen and glucose;
>
> *Part of Claim 53*

The Allen '063 patent teaches a membrane located over at least a portion of the sensor, the membrane comprising a layer configured to control a flux of oxygen and glucose. See the Allen '063 patent, col. 5, lns. 34-43.

The Mastrototaro publication teaches a membrane located over at least a portion of the sensor, the membrane comprising a layer configured to control a flux of oxygen and glucose. See the Mastrototaro publication, pg. 141, stating: "The entire sensor is covered with a differentially permeable biocompatible membrane. This proprietary member is two to three orders of magnitude more permeable to oxygen than glucose, thus compensating for the 'oxygen effect.'"

> wherein the device is capable of exhibiting, at a glucose concentration of 400 mg/dL, no more than a 10% drop in sensor output over a range of pO_2 from 150 mm Hg down to 30 mm Hg;
>
> *Part of Claim 53*

The Allen '063 patent teaches a device is capable of exhibiting, at a glucose concentration of 400 mg/dL, no more than a 10% drop in sensor output over a range of pO_2 from 150 mmHg down to 30 mmHg. See the Allen '063 patent, col. 9, lns. 50-67.

Specifically, the Allen '063 patent presents a sensor system that measures glucose concentrations from 0 to 400 mg/dL, in a fluid with an oxygen concentration ranging from 7 mmHg to 150 mmHg. See the Allen '063 patent, col. 9, lns. 50-68. As such, the ranges disclosed in the Allen '063 patent encompass the ranges claimed in the Shults '562 patent.

The Allen '063 patent further states:

> A computer-controlled system was built to automatically expose sixteen sensors provided with membranes of the invention simultaneously to an array of ***four different glucose concentrations: 0, 100, 200, and 400 mg/dL and four different oxygen concentrations: 1, 2, 5, and 20.9% oxygen (approximately 7-150 mmHg).***
>
> Using this system, it was found that the sensors encapsulated in the membrane ***responded linearly to glucose concentrations ranging***

> ***from 0-400 mg/dL*** (correlation coefficient >0.98) and had a very reproducible baseline value in a buffer solution with no glucose. This characteristic of the sensor allowed a one-point calibration to be adequate. In addition, ***varying the oxygen concentration of the calibration solution between 1 and 20.9% had no effect on the output of the sensor, even at high glucose concentrations. The resolution was better than 10% throughout the entire calibration range*** and the 90% response time for a change in the glucose concentration from 0 to 100 mg/dL was less than 90 seconds.

Id. (emphasis added).

> and wherein the device is configured to respond substantially linearly to changes in glucose concentration at a glucose concentration of up to at least 400 mg/dL.
>
> *Part of Claim 53*

The Allen '063 patent teaches the device is configured to respond substantially linearly to changes in glucose concentration at a glucose concentration of up to about 400 mg/dL. See, for example, the Allen '063 patent, col. 9, lns. 57-61.

12. Dependent Claim 57

In addition to showing each and every feature of claim 53, the Allen '063 patent discloses the features of claim 57, which depends from claim 53.

> Claim 57. The device of claim 53, wherein the membrane comprises a layer comprising an enzyme.

The membrane disclosed in the Allen '063 patent includes an enzyme layer of glucose oxidase (19). See the Allen '063 patent, col. 5, lns. 28-31; and FIG. 2. The Mastrototaro publication teaches a membrane comprising an enzyme layer. See the Mastrototaro publication, pg. 140.

13. Dependent Claim 61

In addition to showing each and every feature of claim 53, the Allen '063 patent discloses the features of claim 61, which depends from claim 53.

> Claim 61. The device of claim 53, wherein the membrane comprises a urethane polymer or a polyurethane.

The Allen '063 patent teaches forming the membrane of a polyurethane. See the Allen '063 patent, col. 5, lns. 44-45.

14. Dependent Claim 72

In addition to showing each and every feature of claim 53, the Allen '063 patent discloses the features of claim 72, which depends from claim 53.

> Claim 72. The device of claim 53, wherein the period of time is at least about 3 days.

The Allen '063 patent demonstrates that the sensor is able to function continuously for at least three days. See, for example, the Allen '063 patent, col. 10, lns. 3-9.

15. Dependent Claim 78

In addition to showing each and every feature of claim 53, the Allen '063 patent discloses the features of claim 78, which depends from claim 53.

> Claim 78. The device of claim 53, wherein the device is configured to be implanted in the host.

The Allen '063 patent teaches configuring the sensor to be implanted in the host. See the Allen '063 patent, col. 10, lns. 10-23.

16. Dependent Claim 79

In addition to showing each and every feature of claim 53, the Allen '063 patent discloses the features of claim 79, which depends from claim 53.

> Claim 79. The device of claim 53, wherein the device is configured to respond substantially linearly to changes in glucose concentration at a glucose concentration of up to at least 400 mg/dL.

The Allen '063 patent teaches the device is configured to respond substantially linearly to changes in glucose concentration at a glucose concentration of up to about 400 mg/dL. See, for example, the Allen '063 patent, col. 9, lns. 57-61.

17. Independent Claim 80

> Claim 80. A device for measuring a glucose concentration in a host, the device comprising:
>
> *Part of Claim 80*

The Allen '063 patent teaches a device for measuring glucose concentration in a host. See the Allen '063 patent, Abstract. The Allen '063 patent incorporates by reference the Mastrototaro publication. See the Allen '063 patent, col. 9, lns. 23-29.

The Mastrototaro publication teaches a device for measuring glucose concentration in a host. See the Mastrototaro publication, Abstract; and pg. 143, Discussion.

> a sensor operably connected to an electronic circuit and configured to continuously measure a signal indicative of a glucose concentration in a host for a period of time; and
>
> *Part of Claim 80*

The Allen '063 patent teaches a sensor operably connected to an electronic circuit and configured to continuously measure a signal indicative of a glucose concentration in a host for a period of time. See the Allen '063 patent, col. 5, lns. 7-15.

The Mastrototaro publication teaches a sensor operably connected to an electronic circuit and configured to continuously measure a signal indicative of a glucose concentration in a host for a period of time. See the Mastrototaro publication, pgs. 140-141.

> a membrane located over at least a portion of the sensor, the membrane comprising a layer configured to control a flux of oxygen and glucose;
>
> *Part of Claim 80*

The Allen '063 patent teaches a membrane located over at least a portion of the sensor, the membrane comprising a layer configured to control a flux of oxygen and glucose. See the Allen '063 patent, col. 5, lns. 34-43.

The Mastrototaro publication teaches a membrane located over at least a portion of the sensor, the membrane comprising a layer configured to control a flux of oxygen and glucose. See the Mastrototaro publication, pg. 141, stating: "The entire sensor is covered with a differentially permeable biocompatible membrane. This proprietary member is two to three

orders of magnitude more permeable to oxygen than glucose, thus compensating for the 'oxygen effect.'"

> wherein the device is capable of exhibiting, at a glucose concentration of 400 mg/dL, no more than a 10% drop in sensor output over a range of pO_2 from 150 mm Hg down to 30 mm Hg;
>
> *Part of Claim 80*

The Allen '063 patent teaches a device is capable of exhibiting, at a glucose concentration of 400 mg/dL, no more than a 10% drop in sensor output over a range of pO_2 from 150 mmHg down to 30 mmHg. See the Allen '063 patent, col. 9, lns. 50-67.

Specifically, the Allen '063 patent presents a sensor system that measures glucose concentrations from 0 to 400 mg/dL, in a fluid with an oxygen concentration ranging from 7 mmHg to 150 mmHg. See the Allen '063 patent, col. 9, lns. 50-68. As such, the ranges disclosed in the Allen '063 patent encompass the ranges claimed in the Shults '562 patent.

The Allen '063 patent further states:

> A computer-controlled system was built to automatically expose sixteen sensors provided with membranes of the invention simultaneously to an array of ***four different glucose concentrations: 0, 100, 200, and 400 mg/dL and four different oxygen concentrations: 1, 2, 5, and 20.9% oxygen (approximately 7-150 mmHg).***
>
> Using this system, it was found that the sensors encapsulated in the membrane ***responded linearly to glucose concentrations ranging from 0-400 mg/dL*** (correlation coefficient >0.98) and had a very reproducible baseline value in a buffer solution with no glucose. This characteristic of the sensor allowed a one-point calibration to be adequate. In addition, ***varying the oxygen concentration of the calibration solution between 1 and 20.9% had no effect on the output of the sensor, even at high glucose concentrations. The resolution was better than 10% throughout the entire calibration range*** and the 90% response time for a change in the glucose concentration from 0 to 100 mg/dL was less than 90 seconds.

Id. (emphasis added).

> and wherein the device is capable of attaining a 90% time response to a 100 mg/dL glucose concentration step in less than 5 minutes.
>
> *Part of Claim 80*

The Allen '063 patent teaches "the 90% response time for a change in the glucose concentration from 0 to 100 mg/dL was less than 90 seconds" (i.e., less than five minutes). See the Allen '063 patent, col. 9, ln. 68 – col. 10, ln. 2.

18. Dependent Claim 84

In addition to showing each and every feature of claim 80, the Allen '063 patent discloses the features of claim 84, which depends from claim 80.

> Claim 84. The device of claim 80, wherein the membrane comprises a layer comprising an enzyme.

The membrane disclosed in the Allen '063 patent includes an enzyme layer of glucose oxidase (19). See the Allen '063 patent, col. 5, lns. 28-31; and FIG. 2. The Mastrototaro publication teaches a membrane comprising an enzyme layer. See the Mastrototaro publication, pg. 140.

19. Dependent Claim 88

In addition to showing each and every feature of claim 80, the Allen '063 patent discloses the features of claim 88, which depends from claim 80.

> Claim 88. The device of claim 80, wherein the membrane comprises a urethane polymer or a polyurethane.

The Allen '063 patent teaches forming the membrane of a polyurethane. See the Allen '063 patent, col. 5, lns. 44-45.

20. Dependent Claim 99

In addition to showing each and every feature of claim 80, the Allen '063 patent discloses the features of claim 99, which depends from claim 80.

> Claim 99. The device of claim 80, wherein the period of time is at least about 3 days.

The Allen '063 patent demonstrates that the sensor is able to function continuously for at least three days. See, for example, the Allen '063 patent, col. 10, lns. 3-9.

21. Dependent Claim 105

In addition to showing each and every feature of claim 80, the Allen '063 patent discloses the features of claim 105, which depends from claim 80.

> Claim 105. The device of claim 80, wherein the device is configured to be implanted in the host.

The Allen '063 patent teaches configuring the sensor to be implanted in the host. See the Allen '063 patent, col. 10, lns. 10-23.

22. Dependent Claim 106

In addition to showing each and every feature of claim 80, the Allen '063 patent discloses the features of claim 106, which depends from claim 80.

> Claim 106. The device of claim 80, wherein the device is configured to respond substantially linearly to changes in glucose concentration at a glucose concentration of up to at least 400 mg/dL.

The Allen '063 patent teaches the device is configured to respond substantially linearly to changes in glucose concentration at a glucose concentration of up to about 400 mg/dL. See, for example, the Allen '063 patent, col. 9, lns. 57-61.

23. Independent Claim 107

> Claim 107. A device for measuring a glucose concentration in a host, the device comprising:
>
> *Part of Claim 107*

The Allen '063 patent teaches a device for measuring glucose concentration in a host. See the Allen '063 patent, Abstract. The Allen '063 patent incorporates by reference the Mastrototaro publication. See the Allen '063 patent, col. 9, lns. 23-29.

The Mastrototaro publication teaches a device for measuring glucose concentration in a host. See the Mastrototaro publication, Abstract; and pg. 143, Discussion.

> a sensor operably connected to an electronic circuit and configured to continuously measure a signal indicative of a glucose concentration in a host for a period of time; and
>
> *Part of Claim 107*

The Allen '063 patent teaches a sensor operably connected to an electronic circuit and configured to continuously measure a signal indicative of a glucose concentration in a host for a period of time. See the Allen '063 patent, col. 5, lns. 7-15.

The Mastrototaro publication teaches a sensor operably connected to an electronic circuit and configured to continuously measure a signal indicative of a glucose concentration in a host for a period of time. See the Mastrototaro publication, pgs. 140-141.

> a membrane located over at least a portion of the sensor, wherein the membrane comprises a layer configured to control a flux of oxygen and glucose,
>
> *Part of Claim 107*

The Allen '063 patent teaches a membrane located over at least a portion of the sensor, the membrane comprising a layer configured to control a flux of oxygen and glucose. See the Allen '063 patent, col. 5, lns. 34-43.

The Mastrototaro publication teaches a membrane located over at least a portion of the sensor, the membrane comprising a layer configured to control a flux of oxygen and glucose. See the Mastrototaro publication, pg. 141, stating: "The entire sensor is covered with a differentially permeable biocompatible membrane. This proprietary member is two to three orders of magnitude more permeable to oxygen than glucose, thus compensating for the 'oxygen effect.'"

> wherein the layer comprises a polyurethane or urethane polymer; wherein the device is capable of exhibiting, at a glucose concentration of 400 mg/dL, no more than a 10% drop in sensor output over a range of pO_2 from 150 mm Hg down to 30 mm Hg.
>
> *Part of Claim 107*

The Allen '063 patent teaches a device is capable of exhibiting, at a glucose concentration of 400 mg/dL, no more than a 10% drop in sensor output over a range of pO_2 from 150 mmHg down to 30 mmHg. See the Allen '063 patent, col. 9, lns. 50-67.

Specifically, the Allen '063 patent presents a sensor system that measures glucose concentrations from 0 to 400 mg/dL, in a fluid with an oxygen concentration ranging from 7 mmHg to 150 mmHg. See the Allen '063 patent, col. 9, lns. 50-68. As such, the ranges disclosed in the Allen '063 patent encompass the ranges claimed in the Shults '562 patent.

The Allen '063 patent further states:

> A computer-controlled system was built to automatically expose sixteen sensors provided with membranes of the invention simultaneously to an array of ***four different glucose concentrations: 0, 100, 200, and 400 mg/dL and four different oxygen concentrations: 1, 2, 5, and 20.9% oxygen (approximately 7-150 mmHg).***
>
> Using this system, it was found that the sensors encapsulated in the membrane ***responded linearly to glucose concentrations ranging from 0-400 mg/dL*** (correlation coefficient >0.98) and had a very reproducible baseline value in a buffer solution with no glucose. This characteristic of the sensor allowed a one-point calibration to be adequate. In addition, ***varying the oxygen concentration of the calibration solution between 1 and 20.9% had no effect on the output of the sensor, even at high glucose concentrations. The resolution was better than 10% throughout the entire calibration range*** and the 90% response time for a change in the glucose concentration from 0 to 100 mg/dL was less than 90 seconds.

Id. (emphasis added).

24. Dependent Claim 111

In addition to showing each and every feature of claim 107, the Allen '063 patent discloses the features of claim 111, which depends from claim 107.

Claim 111. The device of claim 107, wherein the membrane comprises a layer comprising an enzyme.

The membrane disclosed in the Allen '063 patent includes an enzyme layer of glucose oxidase (19). See the Allen '063 patent, col. 5, lns. 28-31; and FIG. 2. The Mastrototaro publication teaches a membrane comprising an enzyme layer. See the Mastrototaro publication, pg. 140.

25. Dependent Claim 125

In addition to showing each and every feature of claim 107, the Allen '063 patent discloses the features of claim 125, which depends from claim 107.

> Claim 125. The device of claim 107, wherein the period of time is at least about 3 days.

The Allen '063 patent demonstrates that the sensor is able to function continuously for at least three days. See, for example, the Allen '063 patent, col. 10, lns. 3-9.

26. Dependent Claim 131

In addition to showing each and every feature of claim 107, the Allen '063 patent discloses the features of claim 131, which depends from claim 107.

> Claim 131. The device of claim 107, wherein the device is configured to be implanted in the host.

The Allen '063 patent teaches configuring the sensor to be implanted in the host. See the Allen '063 patent, col. 10, lns. 10-23.

27. Dependent Claim 132

In addition to showing each and every feature of claim 107, the Allen '063 patent discloses the features of claim 132, which depends from claim 107.

> Claim 132. The device of claim 107, wherein the device is configured to respond substantially linearly to changes in glucose concentration at a glucose concentration of up to at least 400 mg/dL.

The Allen '063 patent teaches the device is configured to respond substantially linearly to changes in glucose concentration at a glucose concentration of up to about 400 mg/dL. See, for example, the Allen '063 patent, col. 9, lns. 57-61.

B. Claims 15, 21, 22, 42, 48, 49, 67, 73, 74, 94, 100, 101, 120, 126, and 127 are obvious under 35 U.S.C. § 103 in view of the Allen '063 patent and the Moatti-Sirat publication.

Claims 15, 21, 22, 42, 48, 49, 67, 73, 74, 94, 100, 101, 120, 126, and 127 are unpatentable under 35 U.S.C. § 103(a) over the Allen '063 patent in view of the Moatti-Sirat publication. Sections VI.B.1 – VI.B.15 detail how claims 15, 21, 22, 42, 48, 49, 67, 73, 74, 94, 100, 101, 120, 126, and 127 are rendered obvious by the combination of the Allen '063 patent

and the Moatti-Sirat publication. For the examiner's convenience, the arguments presented herein are summarized in the table provided in **Exhibit I**.

1. Dependent Claim 15

As outlined above, claim 1 is anticipated by the Allen '063 patent. The features of claim 15, which depends from claim 1, are taught by the Moatti-Sirat publication. One of skill in the art would understand how to modify the teachings of the Allen '063 patent, in view of the Moatti-Sirat publication, to meet the features of claim 15. As such, claim 15 would be obvious under 35 U.S.C. § 103.

> Claim 15. The device of claim 1, wherein at least 95% of glucose concentration values measured by the device are within 25% of corresponding values determined by analysis of blood over the period of time.

The Moatti-Sirat publication teaches a glucose sensor for implantation in the subcutaneous tissue of an animal. See the Moatti-Sirat publication, Summary, pg. 224. The Moatti-Sirat publication teaches a membrane disposed over the glucose sensor. See the Moatti-Sirat publication, pg. 225. Further, page 225 and Table 1 of the Moatti-Sirat publication teaches that the electrode is configured to measure a current produced by the electrode with substantial linearity up to a glucose concentration of 22 mM (i.e., 400 mg/dL).

With regard to the claimed accuracy of the device of claim 15, The Moatti-Sirat publication uses the error grid analysis (EGA) of the Clark publication to present its experimental results.[2] The experimental results of the Moatti-Sirat publication, in turn, fall within the accuracy standard called for in claim 15. For example, the Moatti-Sirat publication teaches that subcutaneous glucose concentrations determined by an implanted sensor are correlated with "reference blood glucose" obtained from a tail vein sample. See the Moatti-Sirat publication, page 225. The correlation between the glucose concentration values measured by

[2] As explained in the Clarke publication, values that fall within Zone A of the error grid do not deviate from a reference value by more than 20%. Values falling within Zone A are considered "clinically accurate" in that they would lead to clinically correct treatment decisions. Values falling within upper and lower Zone B deviate from the reference by more than 20%, but would lead to benign treatment decisions. Values in Zone A and Zone B are considered clinically acceptable. However, values in Zones C, D, and/or E are clinically significant errors and are considered potentially dangerous in that they may call for an erroneous treatment. See the Clarke publication, page. 624 (Exhibit F).

the device and the reference sensor is depicted in FIG. 6 (reproduced below) and described on page 227.

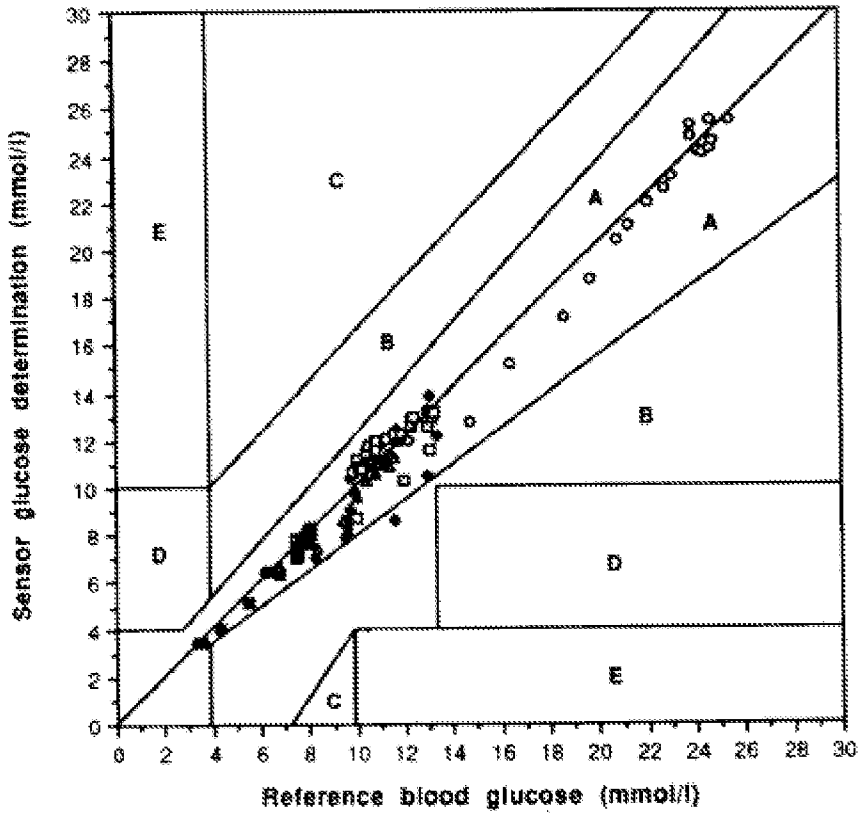

Fig.6. Error grid analysis for estimation of the accuracy of sensor generated blood glucose values, ten days after implantation

As shown in FIG. 6, and described on page 227, 100 of 101 (i.e., 99%) of the experimental values fall within Zone A, which deviates no more than 20% from the reference. In other words, 99% of glucose concentration values measured by the signal are within 20% of one or more reference values. As such, the sensor/membrane combination described and tested in the Moatti-Sirat publication meets the claimed accuracy standard of "at least 95% of glucose concentration values measured by the device are within 25% of corresponding values determined by analysis of blood over the period of time."

Accordingly, one of skill in the art would understand how to modify the sensor of the Allen '063 patent by including the sensor/membrane combination described and tested in the Moatti-Sirat publication and arrive at the features of claim 15. Such a modification of the Allen '063 patent would simply be a combination of prior art elements according to their established

functions, as noted above, and would be within the capabilities of a person having ordinary skill in the art.

2. Dependent Claim 21

As outlined above, claim 1 is anticipated by the Allen '063 patent. The features of claim 21, which depends from claim 1, are taught by the Moatti-Sirat publication. One of skill in the art would understand how to modify the teachings of the Allen '063 patent, in view of the Moatti-Sirat publication, to meet the features of claim 21. As such, claim 21 would be obvious under 35 U.S.C. § 103.

> Claim 21. The device of claim 1, wherein the period of time is at least about 5 days.

The Allen '063 patent demonstrates that the sensor is able to function continuously for at least three days. See, for example, the Allen '063 patent, col. 10, lns. 3-9.

The Moatti-Sirat publication teaches a device (e.g., miniaturized glucose sensor) comprising electrodes configured for implantation in a subcutaneous tissue of the host for at least 10 days. See, for example, the Moatti-Sirat publication, Summary, and pgs. 224 and 228.

3. Dependent Claim 22

As outlined above, claim 1 is anticipated by the Allen '063 patent. The features of claim 22, which depends from claim 1, are taught by the Moatti-Sirat publication. One of skill in the art would understand how to modify the teachings of the Allen '063 patent, in view of the Moatti-Sirat publication, to meet the features of claim 22. As such, claim 22 would be obvious under 35 U.S.C. § 103.

> Claim 22. The device of claim 1, wherein the period of time is at least about 7 days.

The Allen '063 patent demonstrates that the sensor is able to function continuously for at least three days. See, for example, the Allen '063 patent, col. 10, lns. 3-9.

The Moatti-Sirat publication teaches a device (e.g., miniaturized glucose sensor) comprising electrodes configured for implantation in a subcutaneous tissue of the host for at least 10 days. See, for example, the Moatti-Sirat publication, Summary, and pgs. 224 and 228.

4. Dependent Claim 42

As outlined above, claim 28 is anticipated by the Allen '063 patent. The features of claim 42, which depends from claim 28, are taught by the Moatti-Sirat publication. One of skill in the art would understand how to modify the teachings of the Allen '063 patent, in view of the Moatti-Sirat publication, to meet the features of claim 42. As such, claim 42 would be obvious under 35 U.S.C. § 103.

> Claim 42. The device of claim 28, wherein at least 95% of glucose concentration values measured by the device are within 25% of corresponding values determined by analysis of blood over the period of time.

The Moatti-Sirat publication teaches a glucose sensor for implantation in the subcutaneous tissue of an animal. See the Moatti-Sirat publication, Summary, pg. 224. The Moatti-Sirat publication teaches a membrane disposed over the glucose sensor. See the Moatti-Sirat publication, pg. 225. Further, page 225 and Table 1 of the Moatti-Sirat publication teaches that the electrode is configured to measure a current produced by the electrode with substantial linearity up to a glucose concentration of 22 mM (i.e., 400 mg/dL).

With regard to the claimed accuracy of the device of claim 42, The Moatti-Sirat publication uses the EGA of the Clark publication to present its experimental results. The experimental results of the Moatti-Sirat publication, in turn, fall within the accuracy standard called for in claim 42. For example, the Moatti-Sirat publication teaches that subcutaneous glucose concentrations determined by an implanted sensor are correlated with "reference blood glucose" obtained from a tail vein sample. See the Moatti-Sirat publication, page 225. The correlation between the glucose concentration values measured by the device and the reference sensor is depicted in FIG. 6 (reproduced below) and described on page 227.

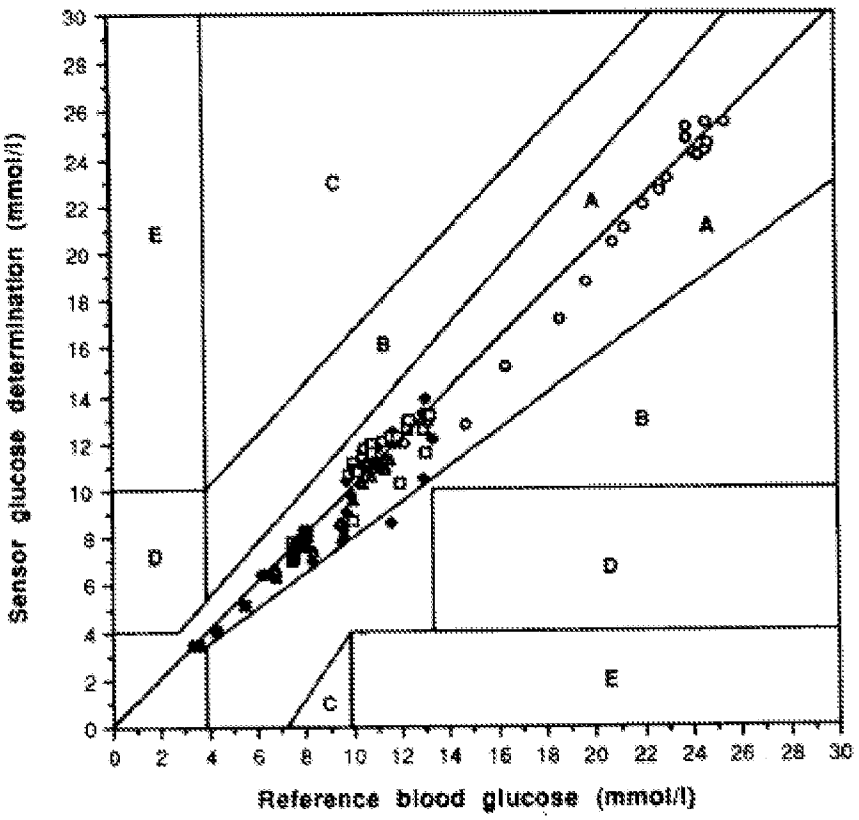

Fig. 6. Error grid analysis for estimation of the accuracy of sensor generated blood glucose values, ten days after implantation

As shown in FIG. 6, and described on page 227, 100 of 101 (i.e., 99%) of the experimental values fall within Zone A, which deviates no more than 20% from the reference. In other words, 99% of glucose concentration values measured by the signal are within 20% of one or more reference values. As such, the sensor/membrane combination described and tested in the Moatti-Sirat publication meets the claimed accuracy standard of "at least 95% of glucose concentration values measured by the device are within 25% of corresponding values determined by analysis of blood over the period of time."

Accordingly, one of skill in the art would understand how to modify the sensor of the Allen '063 patent by including the sensor/membrane combination described and tested in the Moatti-Sirat publication and arrive at the features of claim 42. Such a modification of the Allen '063 patent would simply be a combination of prior art elements according to their established functions, as noted above, and would be within the capabilities of a person having ordinary skill in the art.

5. Dependent Claim 48

As outlined above, claim 28 is anticipated by the Allen '063 patent. The features of claim 48, which depends from claim 28, are taught by the Moatti-Sirat publication. One of skill in the art would understand how to modify the teachings of the Allen '063 patent, in view of the Moatti-Sirat publication, to meet the features of claim 48. As such, claim 48 would be obvious under 35 U.S.C. § 103.

> Claim 48. The device of claim 28, wherein the period of time is at least about 5 days.

The Allen '063 patent demonstrates that the sensor is able to function continuously for at least three days. See, for example, the Allen '063 patent, col. 10, lns. 3-9.

The Moatti-Sirat publication teaches a device (e.g., miniaturized glucose sensor) comprising electrodes configured for implantation in a subcutaneous tissue of the host for at least 10 days. See, for example, the Moatti-Sirat publication, Summary, and pgs. 224 and 228.

6. Dependent Claim 49

As outlined above, claim 28 is anticipated by the Allen '063 patent. The features of claim 49, which depends from claim 28, are taught by the Moatti-Sirat publication. One of skill in the art would understand how to modify the teachings of the Allen '063 patent, in view of the Moatti-Sirat publication, to meet the features of claim 49. As such, claim 49 would be obvious under 35 U.S.C. § 103.

> Claim 49. The device of claim 28, wherein the period of time is at least about 7 days.

The Allen '063 patent demonstrates that the sensor is able to function continuously for at least three days. See, for example, the Allen '063 patent, col. 10, lns. 3-9.

The Moatti-Sirat publication teaches a device (e.g., miniaturized glucose sensor) comprising electrodes configured for implantation in a subcutaneous tissue of the host for at least 10 days. See, for example, the Moatti-Sirat publication, Summary, and pgs. 224 and 228.

7. Dependent Claim 67

As outlined above, claim 53 is anticipated by the Allen '063 patent. The features of claim 67, which depends from claim 53, are taught by the Moatti-Sirat publication. One of skill

in the art would understand how to modify the teachings of the Allen '063 patent, in view of the Moatti-Sirat publication, to meet the features of claim 67. As such, claim 67 would be obvious under 35 U.S.C. § 103.

> Claim 67. The device of claim 53, wherein at least 95% of glucose concentration values measured by the device are within 25% of corresponding values determined by analysis of blood over the period of time.

The Moatti-Sirat publication teaches a glucose sensor for implantation in the subcutaneous tissue of an animal. See the Moatti-Sirat publication, Summary, pg. 224. The Moatti-Sirat publication teaches a membrane disposed over the glucose sensor. See the Moatti-Sirat publication, pg. 225. Further, page 225 and Table 1 of the Moatti-Sirat publication teaches that the electrode is configured to measure a current produced by the electrode with substantial linearity up to a glucose concentration of 22 mM (i.e., 400 mg/dL).

With regard to the claimed accuracy of the device of claim 67, The Moatti-Sirat publication uses the EGA of the Clark publication to present its experimental results. The experimental results of the Moatti-Sirat publication, in turn, fall within the accuracy standard called for in claim 67. For example, the Moatti-Sirat publication teaches that subcutaneous glucose concentrations determined by an implanted sensor are correlated with "reference blood glucose" obtained from a tail vein sample. See the Moatti-Sirat publication, page 225. The correlation between the glucose concentration values measured by the device and the reference sensor is depicted in FIG. 6 (reproduced below) and described on page 227.

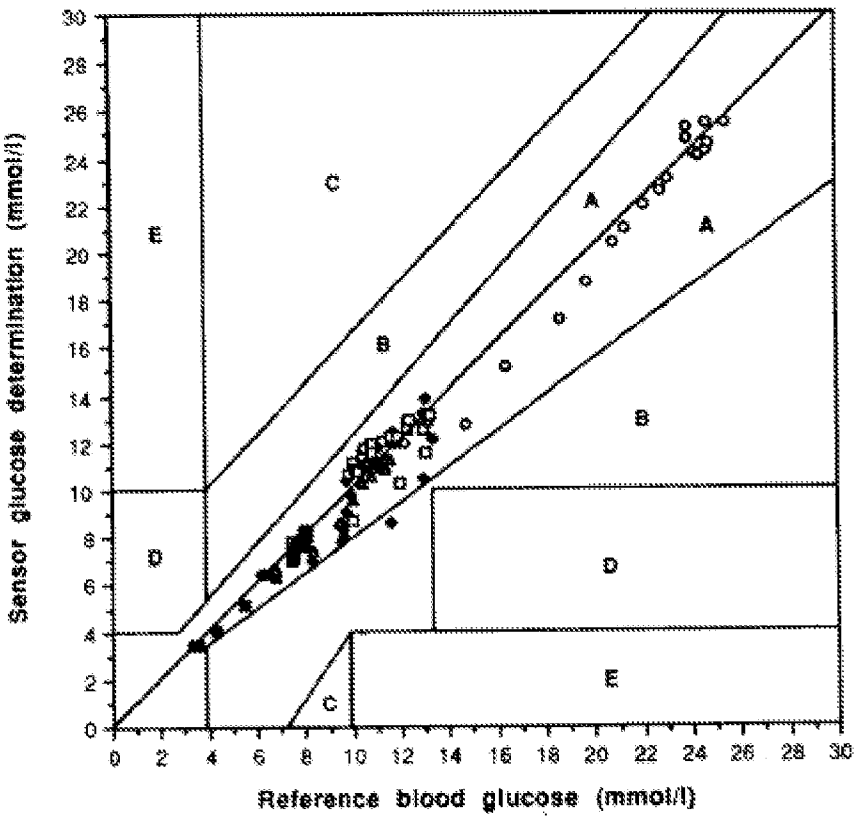

Fig. 6. Error grid analysis for estimation of the accuracy of sensor generated blood glucose values, ten days after implantation

As shown in FIG. 6, and described on page 227, 100 of 101 (i.e., 99%) of the experimental values fall within Zone A, which deviates no more than 20% from the reference. In other words, 99% of glucose concentration values measured by the signal are within 20% of one or more reference values. As such, the sensor/membrane combination described and tested in the Moatti-Sirat publication meets the claimed accuracy standard of "at least 95% of glucose concentration values measured by the device are within 25% of corresponding values determined by analysis of blood over the period of time."

Accordingly, one of skill in the art would understand how to modify the sensor of the Allen '063 patent by including the sensor/membrane combination described and tested in the Moatti-Sirat publication and arrive at the features of claim 67. Such a modification of the Allen '063 patent would simply be a combination of prior art elements according to their established functions, as noted above, and would be within the capabilities of a person having ordinary skill in the art.

8. Dependent Claim 73

As outlined above, claim 53 is anticipated by the Allen '063 patent. The features of claim 73, which depends from claim 53, are taught by the Moatti-Sirat publication. One of skill in the art would understand how to modify the teachings of the Allen '063 patent, in view of the Moatti-Sirat publication, to meet the features of claim 73. As such, claim 73 would be obvious under 35 U.S.C. § 103.

> Claim 73. The device of claim 53, wherein the period of time is at least about 5 days.

The Allen '063 patent demonstrates that the sensor is able to function continuously for at least three days. See, for example, the Allen '063 patent, col. 10, lns. 3-9.

The Moatti-Sirat publication teaches a device (e.g., miniaturized glucose sensor) comprising electrodes configured for implantation in a subcutaneous tissue of the host for at least 10 days. See, for example, the Moatti-Sirat publication, Summary, and pgs. 224 and 228.

9. Dependent Claim 74

As outlined above, claim 53 is anticipated by the Allen '063 patent. The features of claim 74, which depends from claim 53, are taught by the Moatti-Sirat publication. One of skill in the art would understand how to modify the teachings of the Allen '063 patent, in view of the Moatti-Sirat publication, to meet the features of claim 74. As such, claim 74 would be obvious under 35 U.S.C. § 103.

> Claim 74. The device of claim 53, wherein the period of time is at least about 7 days.

The Allen '063 patent demonstrates that the sensor is able to function continuously for at least three days. See, for example, the Allen '063 patent, col. 10, lns. 3-9.

The Moatti-Sirat publication teaches a device (e.g., miniaturized glucose sensor) comprising electrodes configured for implantation in a subcutaneous tissue of the host for at least 10 days. See, for example, the Moatti-Sirat publication, Summary, and pgs. 224 and 228.

10. Dependent Claim 94

As outlined above, claim 80 is anticipated by the Allen '063 patent. The features of claim 94, which depends from claim 80, are taught by the Moatti-Sirat publication. One of skill

in the art would understand how to modify the teachings of the Allen '063 patent, in view of the Moatti-Sirat publication, to meet the features of claim 94. As such, claim 94 would be obvious under 35 U.S.C. § 103.

> Claim 94. The device of claim 80, wherein at least 95% of glucose concentration values measured by the device are within 25% of corresponding values determined by analysis of blood over the period of time.

The Moatti-Sirat publication teaches a glucose sensor for implantation in the subcutaneous tissue of an animal. See the Moatti-Sirat publication, Summary, pg. 224. The Moatti-Sirat publication teaches a membrane disposed over the glucose sensor. See the Moatti-Sirat publication, pg. 225. Further, page 225 and Table 1 of the Moatti-Sirat publication teaches that the electrode is configured to measure a current produced by the electrode with substantial linearity up to a glucose concentration of 22 mM (i.e., 400 mg/dL).

With regard to the claimed accuracy of the device of claim 94, The Moatti-Sirat publication uses the EGA of the Clark publication to present its experimental results. The experimental results of the Moatti-Sirat publication, in turn, fall within the accuracy standard called for in claim 94. For example, the Moatti-Sirat publication teaches that subcutaneous glucose concentrations determined by an implanted sensor are correlated with "reference blood glucose" obtained from a tail vein sample. See the Moatti-Sirat publication, page 225. The correlation between the glucose concentration values measured by the device and the reference sensor is depicted in FIG. 6 (reproduced below) and described on page 227.

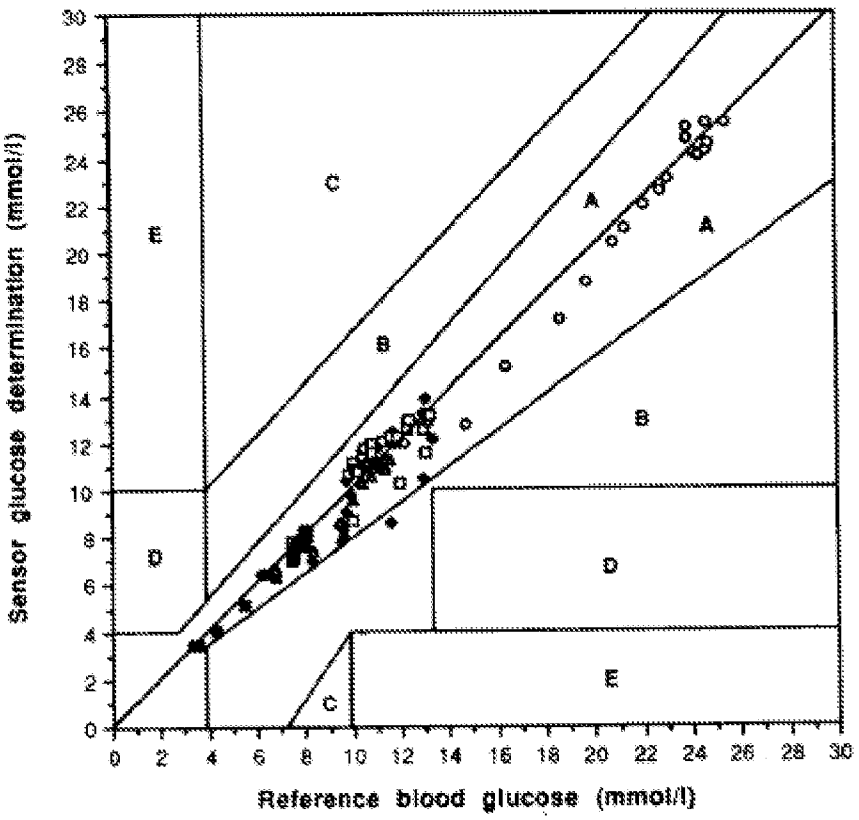

Fig. 6. Error grid analysis for estimation of the accuracy of sensor generated blood glucose values, ten days after implantation

As shown in FIG. 6, and described on page 227, 100 of 101 (i.e., 99%) of the experimental values fall within Zone A, which deviates no more than 20% from the reference. In other words, 99% of glucose concentration values measured by the signal are within 20% of one or more reference values. As such, the sensor/membrane combination described and tested in the Moatti-Sirat publication meets the claimed accuracy standard of "at least 95% of glucose concentration values measured by the device are within 25% of corresponding values determined by analysis of blood over the period of time."

Accordingly, one of skill in the art would understand how to modify the sensor of the Allen '063 patent by including the sensor/membrane combination described and tested in the Moatti-Sirat publication and arrive at the features of claim 94. Such a modification of the Allen '063 patent would simply be a combination of prior art elements according to their established functions, as noted above, and would be within the capabilities of a person having ordinary skill in the art.

11. Dependent Claim 100

As outlined above, claim 80 is anticipated by the Allen '063 patent. The features of claim 100, which depends from claim 80, are taught by the Moatti-Sirat publication. One of skill in the art would understand how to modify the teachings of the Allen '063 patent, in view of the Moatti-Sirat publication, to meet the features of claim 100. As such, claim 100 would be obvious under 35 U.S.C. § 103.

> Claim 100. The device of claim 80, wherein the period of time is at least about 5 days.

The Allen '063 patent demonstrates that the sensor is able to function continuously for at least three days. See, for example, the Allen '063 patent, col. 10, lns. 3-9.

The Moatti-Sirat publication teaches a device (e.g., miniaturized glucose sensor) comprising electrodes configured for implantation in a subcutaneous tissue of the host for at least 10 days. See, for example, the Moatti-Sirat publication, Summary, and pgs. 224 and 228.

12. Dependent Claim 101

As outlined above, claim 80 is anticipated by the Allen '063 patent. The features of claim 101, which depends from claim 80, are taught by the Moatti-Sirat publication. One of skill in the art would understand how to modify the teachings of the Allen '063 patent, in view of the Moatti-Sirat publication, to meet the features of claim 101. As such, claim 101 would be obvious under 35 U.S.C. § 103.

> Claim 101. The device of claim 80, wherein the period of time is at least about 7 days.

The Allen '063 patent demonstrates that the sensor is able to function continuously for at least three days. See, for example, the Allen '063 patent, col. 10, lns. 3-9.

The Moatti-Sirat publication teaches a device (e.g., miniaturized glucose sensor) comprising electrodes configured for implantation in a subcutaneous tissue of the host for at least 10 days. See, for example, the Moatti-Sirat publication, Summary, and pgs. 224 and 228.

13. Dependent Claim 120

As outlined above, claim 107 is anticipated by the Allen '063 patent. The features of claim 120, which depends from claim 107, are taught by the Moatti-Sirat publication. One of skill in the art would understand how to modify the teachings of the Allen '063 patent, in view of the Moatti-Sirat publication, to meet the features of claim 120 As such, claim 120 would be obvious under 35 U.S.C. § 103.

> Claim 120. The device of claim 107, wherein at least 95% of glucose concentration values measured by the device are within 25% of corresponding values determined by analysis of blood over the period of time.

The Moatti-Sirat publication teaches a glucose sensor for implantation in the subcutaneous tissue of an animal. See the Moatti-Sirat publication, Summary, pg. 224. The Moatti-Sirat publication teaches a membrane disposed over the glucose sensor. See the Moatti-Sirat publication, pg. 225. Further, page 225 and Table 1 of the Moatti-Sirat publication teaches that the electrode is configured to measure a current produced by the electrode with substantial linearity up to a glucose concentration of 22 mM (i.e., 400 mg/dL).

With regard to the claimed accuracy of the device of claim 120, The Moatti-Sirat publication uses the EGA of the Clark publication to present its experimental results. The experimental results of the Moatti-Sirat publication, in turn, fall within the accuracy standard called for in claim 120. For example, the Moatti-Sirat publication teaches that subcutaneous glucose concentrations determined by an implanted sensor are correlated with "reference blood glucose" obtained from a tail vein sample. See the Moatti-Sirat publication, page 225. The correlation between the glucose concentration values measured by the device and the reference sensor is depicted in FIG. 6 (reproduced below) and described on page 227.

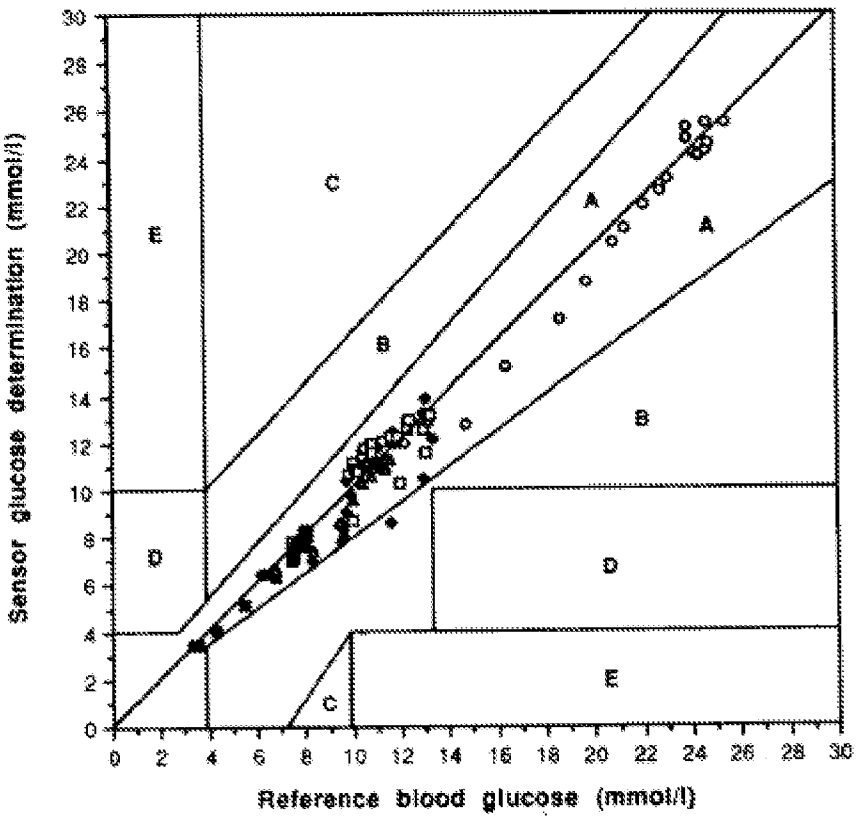

Fig. 6. Error grid analysis for estimation of the accuracy of sensor generated blood glucose values, ten days after implantation

As shown in FIG. 6, and described on page 227, 100 of 101 (i.e., 99%) of the experimental values fall within Zone A, which deviates no more than 20% from the reference. In other words, 99% of glucose concentration values measured by the signal are within 20% of one or more reference values. As such, the sensor/membrane combination described and tested in the Moatti-Sirat publication meets the claimed accuracy standard of "at least 95% of glucose concentration values measured by the device are within 25% of corresponding values determined by analysis of blood over the period of time."

Accordingly, one of skill in the art would understand how to modify the sensor of the Allen '063 patent by including the sensor/membrane combination described and tested in the Moatti-Sirat publication and arrive at the features of claim 120. Such a modification of the Allen '063 patent would simply be a combination of prior art elements according to their established functions, as noted above, and would be within the capabilities of a person having ordinary skill in the art.

14. Dependent Claim 126

As outlined above, claim 107 is anticipated by the Allen '063 patent. The features of claim 126, which depends from claim 107, are taught by the Moatti-Sirat publication. One of skill in the art would understand how to modify the teachings of the Allen '063 patent, in view of the Moatti-Sirat publication, to meet the features of claim 126. As such, claim 126 would be obvious under 35 U.S.C. § 103.

> Claim 126. The device of claim 107, wherein the period of time is at least about 5 days.

The Allen '063 patent demonstrates that the sensor is able to function continuously for at least three days. See, for example, the Allen '063 patent, col. 10, lns. 3-9.

The Moatti-Sirat publication teaches a device (e.g., miniaturized glucose sensor) comprising electrodes configured for implantation in a subcutaneous tissue of the host for at least 10 days. See, for example, the Moatti-Sirat publication, Summary, and pgs. 224 and 228.

15. Dependent Claim 127

As outlined above, claim 107 is anticipated by the Allen '063 patent. The features of claim 127, which depends from claim 107, are taught by the Moatti-Sirat publication. One of skill in the art would understand how to modify the teachings of the Allen '063 patent, in view of the Moatti-Sirat publication, to meet the features of claim 127. As such, claim 127 would be obvious under 35 U.S.C. § 103.

> Claim 127. The device of claim 107, wherein the period of time is at least about 7 days.

The Allen '063 patent demonstrates that the sensor is able to function continuously for at least three days. See, for example, the Allen '063 patent, col. 10, lns. 3-9.

The Moatti-Sirat publication teaches a device (e.g., miniaturized glucose sensor) comprising electrodes configured for implantation in a subcutaneous tissue of the host for at least 10 days. See, for example, the Moatti-Sirat publication, Summary, and pgs. 224 and 228.

C. Claims 25, 52, 77, 104, and 130 are obvious under 35 U.S.C. § 103 in view of the Allen '063 patent and the Csöregi publication.

Claims 25, 52, 77, 104, and 130 are unpatentable under 35 U.S.C. § 103(a) over the Allen '063 patent in view of the Csöregi publication. Sections VI.C.1 – VI.C.5 detail how claims 25, 52, 77, 104, and 130 are rendered obvious by the combination of the Allen '063 patent and the Csöregi publication. For the examiner's convenience, the arguments presented herein are summarized in the table provided in **Exhibit J**.

1. Dependent Claim 25

As outlined above, claim 1 is anticipated by the Allen '063 patent. The features of claim 25, which depends from claim 1, are taught by the Csöregi publication. One of skill in the art would understand how to modify the teachings of the Allen '063 patent, in view of the Csöregi publication, to meet the features of claim 25. As such, claim 25 would be obvious under 35 U.S.C. § 103.

> Claim 25. The device of claim 1, wherein the device is configured for single-point recalibration.

The Csöregi publication teaches a device for measuring glucose concentration in a host. See the Csöregi publication, Abstract. The sensors of the Csöregi publication are configured for single-point recalibration. Specifically, the Csöregi publication states:

> The stability observed and the existence of a valid zero point in the presence of interferants suggested that the sensor could be used in vivo for 72 h and be tested/recalibrated in vivo through a single-point calibration, i.e., by withdrawing only a single sample of blood for independent analysis.

The Csöregi publication, pg. 3136.

Accordingly, one of skill in the art would understand how to modify the sensor of the Allen '063 patent by configuring the sensor for single point recalibration as described in the Csöregi publication and arrive at the features of claim 25. Such a modification of the Allen '063 patent would simply be a combination of prior art elements according to their established functions, as noted above, and would be within the capabilities of a person having ordinary skill in the art.

2. Dependent Claim 52

As outlined above, claim 28 is anticipated by the Allen '063 patent. The features of claim 52, which depends from claim 28, are taught by the Csöregi publication. One of skill in the art would understand how to modify the teachings of the Allen '063 patent, in view of the Csöregi publication, to meet the features of claim 52. As such, claim 52 would be obvious under 35 U.S.C. § 103.

> Claim 52. The device of claim 28, wherein the device is configured for single-point recalibration.

The Csöregi publication teaches a device for measuring glucose concentration in a host. See the Csöregi publication, Abstract. The sensors of the Csöregi publication are configured for single-point recalibration. Specifically, the Csöregi publication states:

> The stability observed and the existence of a valid zero point in the presence of interferants suggested that the sensor could be used in vivo for 72 h and be tested/recalibrated in vivo through a single-point calibration, i.e., by withdrawing only a single sample of blood for independent analysis.

The Csöregi publication, pg. 3136.

Accordingly, one of skill in the art would understand how to modify the sensor of the Allen '063 patent by configuring the sensor for single point recalibration as described in the Csöregi publication and arrive at the features of claim 52. Such a modification of the Allen '063 patent would simply be a combination of prior art elements according to their established functions, as noted above, and would be within the capabilities of a person having ordinary skill in the art.

3. Dependent Claim 77

As outlined above, claim 53 is anticipated by the Allen '063 patent. The features of claim 77, which depends from claim 53, are taught by the Csöregi publication. One of skill in the art would understand how to modify the teachings of the Allen '063 patent, in view of the Csöregi publication, to meet the features of claim 77. As such, claim 77 would be obvious under 35 U.S.C. § 103.

> Claim 77. The device of claim 53, wherein the device is configured for single-point recalibration.

The Csöregi publication teaches a device for measuring glucose concentration in a host. See the Csöregi publication, Abstract. The sensors of the Csöregi publication are configured for single-point recalibration. Specifically, the Csöregi publication states:

> The stability observed and the existence of a valid zero point in the presence of interferants suggested that the sensor could be used in vivo for 72 h and be tested/recalibrated in vivo through a single-point calibration, i.e., by withdrawing only a single sample of blood for independent analysis.

The Csöregi publication, pg. 3136.

Accordingly, one of skill in the art would understand how to modify the sensor of the Allen '063 patent by configuring the sensor for single point recalibration as described in the Csöregi publication and arrive at the features of claim 77. Such a modification of the Allen '063 patent would simply be a combination of prior art elements according to their established functions, as noted above, and would be within the capabilities of a person having ordinary skill in the art.

4. Dependent Claim 104

As outlined above, claim 80 is anticipated by the Allen '063 patent. The features of claim 104, which depends from claim 80, are taught by the Csöregi publication. One of skill in the art would understand how to modify the teachings of the Allen '063 patent, in view of the Csöregi publication, to meet the features of claim 104. As such, claim 104 would be obvious under 35 U.S.C. § 103.

> Claim 104. The device of claim 80, wherein the device is configured for single-point recalibration.

The Csöregi publication teaches a device for measuring glucose concentration in a host. See the Csöregi publication, Abstract. The sensors of the Csöregi publication are configured for single-point recalibration. Specifically, the Csöregi publication states:

> The stability observed and the existence of a valid zero point in the presence of interferants suggested that the sensor could be used in vivo for 72 h and be tested/recalibrated in vivo through a single-

> point calibration, i.e., by withdrawing only a single sample of blood for independent analysis.

The Csöregi publication, pg. 3136.

Accordingly, one of skill in the art would understand how to modify the sensor of the Allen '063 patent by configuring the sensor for single point recalibration as described in the Csöregi publication and arrive at the features of claim 104. Such a modification of the Allen '063 patent would simply be a combination of prior art elements according to their established functions, as noted above, and would be within the capabilities of a person having ordinary skill in the art.

5. Dependent Claim 130

As outlined above, claim 107 is anticipated by the Allen '063 patent. The features of claim 130, which depends from claim 107, are taught by the Csöregi publication. One of skill in the art would understand how to modify the teachings of the Allen '063 patent, in view of the Csöregi publication, to meet the features of claim 130. As such, claim 130 would be obvious under 35 U.S.C. § 103.

> Claim 130. The device of claim 107, wherein the device is configured for single-point recalibration.

The Csöregi publication teaches a device for measuring glucose concentration in a host. See the Csöregi publication, Abstract. The sensors of the Csöregi publication are configured for single-point recalibration. Specifically, the Csöregi publication states:

> The stability observed and the existence of a valid zero point in the presence of interferants suggested that the sensor could be used in vivo for 72 h and be tested/recalibrated in vivo through a single-point calibration, i.e., by withdrawing only a single sample of blood for independent analysis.

The Csöregi publication, pg. 3136.

D. Claims 1, 5, 9, 26, and 27 are obvious under 35 U.S.C. § 103 in view of the Kusano publication and the Mastrototaro publication.

Claims 1, 5, 9, 26, and 27 are unpatentable under 35 U.S.C. § 103(a) over the Kusano publication and the Mastrototaro publication. Sections VI.D.1 – VI.D.5 detail how claims 1, 5, 9, 26, and 27 are rendered obvious by the combination of the Kusano publication and the

Mastrototaro publication. For the examiner's convenience, the arguments presented herein are summarized in the table provided in **Exhibit K**.

1. Independent Claim 1

> Claim 1. A device for measuring a glucose concentration in a host, the device comprising:
>
> *Part of Claim 1*

The Kusano publication teaches a device for measuring glucose concentration in a host. See the Kusano publication, Abstract.

The Mastrototaro publication teaches a device for measuring glucose concentration in a host. See the Mastrototaro publication, Abstract; and pg. 143, Discussion.

> a sensor operably connected to an electronic circuit and configured to continuously measure a signal indicative of a glucose concentration in a host for a period of time; and
>
> *Part of Claim 1*

The Kusano publication teaches a sensor operably connected to an electronic circuit and configured to continuously measure a signal indicative of a glucose concentration in a host for a period of time. See the Kusano publication, Abstract; pgs. 2-3; and Figure 2 (reproduced below).

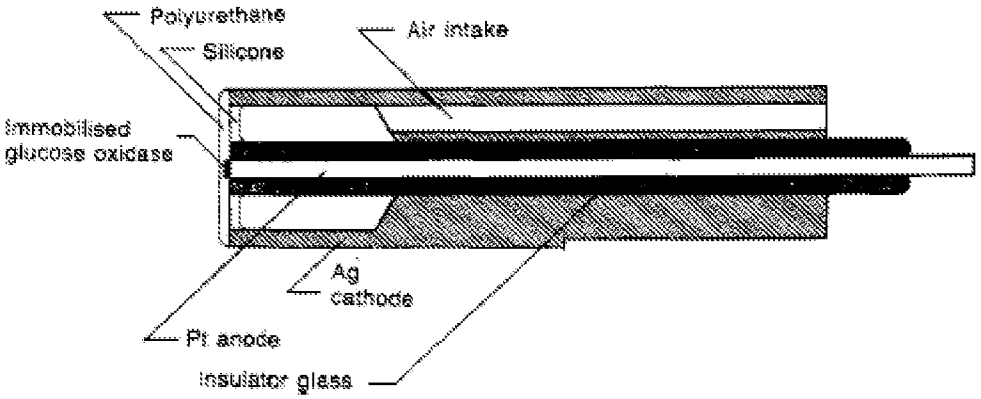

Figure 2. Schematic diagram of the experimental glucose electrode.

The Mastrototaro publication teaches a sensor operably connected to an electronic circuit and configured to continuously measure a signal indicative of a glucose concentration in a host for a period of time. See the Mastrototaro publication, pgs. 140-141.

> a membrane located over at least a portion of the sensor, the membrane comprising a layer configured to control a flux of oxygen and glucose;
>
> *Part of Claim 1*

The Kusano publication teaches a membrane located over at least a portion of the electrode surface, the membrane comprising a layer configured to control a flux of oxygen and glucose. See the Kusano publication, Abstract; pgs. 2-3; and Figure 2 (above).

The Mastrototaro publication teaches a membrane located over at least a portion of the sensor, the membrane comprising a layer configured to control a flux of oxygen and glucose. See the Mastrototaro publication, pg. 141, stating: "The entire sensor is covered with a differentially permeable biocompatible membrane. This proprietary member is two to three orders of magnitude more permeable to oxygen than glucose, thus compensating for the 'oxygen effect.'"

> wherein the device is capable of exhibiting, at a glucose concentration of 400 mg/dL, no more than a 10% drop in sensor output over a range of pO2 from 150 mm Hg down to 30 mm Hg,
>
> *Part of Claim 1*

The Kusano publication teaches a device is capable of exhibiting, at a glucose concentration of 400 mg/dL, no more than a 10% drop in sensor output over a range of pO_2 from 150 mmHg down to 30 mmHg. See the Kusano publication, section 3.4, pgs. 6-7; Figure 8; and Conclusion.

Specifically, the Kusano publication presents a sensor system that measures glucose concentrations from 0 to 500 mg/dL, in a fluid with an oxygen concentration ranging from 0 kPa (0 mmHg) to 20.5 kPa (154 mmHg). See the Kusano publication, pgs. 6-7, and Figure 8. As such, the ranges disclosed in the Kusano publication encompasses the ranges claimed in the Shults '562 patent.

The Kusano publication further states:

> The electrode calibration curve is shown in figure 8. Reproducibility at a glucose concentration of 500 mg dl^{-1} (27.8 mmol l^{-1}) was within an error of ± 3%. ***Oxygen concentration had no effect on electrode response***.

The Kusano publication, pgs. 6-7 (emphasis added).

Figure 8 of the Kusano publication (reproduced below) shows a linear current measurement up to 500 mg/dL, and a negligible drop in sensor output (i.e., "an error of ± 3%") as the pO_2 is varied from 0 kPa (0 mmHg) to 20.5 kPa (154 mmHg).

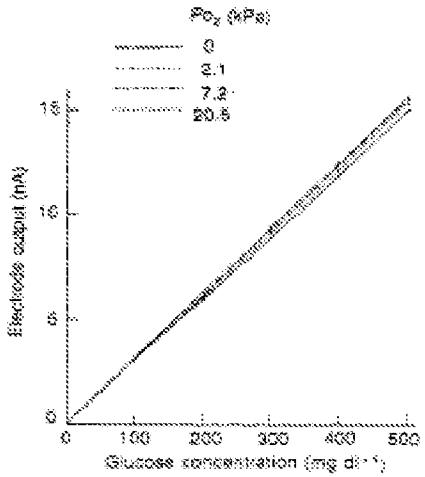

Figure 8. Electrode calibration curves under various Po_2.

The concluding remarks of the Kusano publication further state:

> Glucose concentrations of 0 to 500 mg dl^{-1} (27.8 mmol l^{-1}) could be measured without being affected by oxygen concentration in the range of 0 to 163 mmHg (21.7 kPa).

The Kusano publication, pg. 8.

> and wherein the device is configured to use an in vitro calibration factor for initial calibration.
>
> *Part of Claim 1*

The Kusano publication teaches, "The electrode can be easily calibrated by dismantling from the percutaneous interface frequently." The Kusano publication, pg. 7.

On page 141, the Mastrototaro publication states:

> The sensors have been shown to respond linearly ($R^2 > 0.98$) to glucose concentrations ranging from 0 to 400 mg/dl (Fig. 1). The linearity of response is important because it indicates that a two-point sensor calibration is sufficient. Furthermore, since the sensors have a predetermined and reproducible baseline value, a one-point calibration is possible.

In its concluding remarks, the Mastrototaro publication further states: "Finally, it is important to correlate an *in vitro* calibration of the sensors prior to implantation to *in vivo* response." The Mastrototaro publication, pg. 143, Discussion.

The Kusano publication and the Mastrototaro publication identify and address the same problem addressed by the Shults '562 patent; e.g., the development and testing of an accurate glucose sensor. One of skill in the art could predictably combine the teachings of the Kusano publication with the teachings of the Mastrototaro publication to achieve the device called for in claim 1. The device of claim 1 offers no more than the predictable use of prior art elements according to their established functions. As such, claim 1 would have been obvious to one of skill in the art; particularly in light of the teachings of the Kusano publication and the Mastrototaro publication. Claim 1 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007).

2. Dependent Claim 5

In addition to showing each and every feature of claim 1, the combination of the Kusano publication and the Mastrototaro publication discloses the features of claim 5, which depends from claim 1.

> Claim 5. The device of claim 1, wherein the membrane comprises a layer comprising an enzyme.

The membrane disclosed in the Kusano publication includes an enzyme layer of immobilized glucose oxidase. See the Kusano publication, pg. 3; and Figure 2 (above).

The Mastrototaro publication teaches a membrane comprising an enzyme layer. See the Mastrototaro publication, pg. 140.

3. Dependent Claim 9

In addition to showing each and every feature of claim 1, the combination of the Kusano publication and the Mastrototaro publication discloses the features of claim 9, which depends from claim 1.

> Claim 9. The device of claim 1, wherein the membrane comprises a urethane polymer or a polyurethane.

The Kusano publication teaches forming the membrane of a polyurethane. See the Kusano publication, pg. 3; and Figure 2 (above).

4. Dependent Claim 26

In addition to showing each and every feature of claim 1, the combination of the Kusano publication and the Mastrototaro publication discloses the features of claim 26, which depends from claim 1.

> Claim 26. The device of claim 1, wherein the device is configured to be implanted in the host.

While the sensors of the Kusano publication are tested *in vitro*, they are designed and intended for *in vivo* implantation. See the Kusano publication, Abstract. As such, the Kusano publication teaches a device configure to be implanted in the host.

The Mastrototaro publication teaches the device is configured to be implanted in the host. See the Mastrototaro publication, pg. 141.

5. Dependent Claim 27

In addition to showing each and every feature of claim 1, the combination of the Kusano publication and the Mastrototaro publication discloses the features of claim 27, which depends from claim 1.

> Claim 27. The device of claim 1, wherein the device is configured to respond substantially linearly to changes in glucose concentration at a glucose concentration of up to at least 400 mg/dL.

As shown in Figure 8 above, the sensor of the Kusano publication responds substantially linearly to changes in glucose concentration at a glucose concentration of up to at least 400 mg/dL.

As shown in Fig. 1 (reproduced below), and discussed on page 141, the Mastrototaro publication shows a sensor configured to respond substantially linearly to changes in glucose concentration at a glucose concentration of up to at least 400 mg/dL.

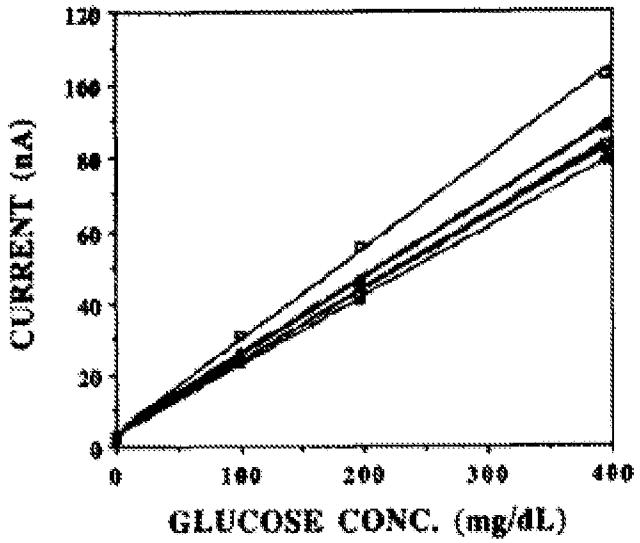

Fig. 1. Glucose calibration data from six sensors *in vitro*. The current output (nA) is plotted vs. the glucose concentration (mg/dl).

E. Claims 15, and 20-22 are obvious under 35 U.S.C. § 103 in view of the Kusano publication, the Mastrototaro publication, and the Moatti-Sirat publication.

Claims 15 and 20-22 are unpatentable under 35 U.S.C. § 103(a) over the Kusano publication in view of the Mastrototaro publication, and further in view of the Moatti-Sirat publication. Sections VI.E.1 – VI.E.4 detail how claims 15 and 20-22 are rendered obvious by the combination of the Kusano publication, the Mastrototaro publication, and the Moatti-Sirat publication. For the examiner's convenience, the arguments presented herein are summarized in the table provided in **Exhibit L**.

1. Dependent Claim 15

As outlined above, claim 1 is rendered obvious by the combination of the Kusano publication and the Mastrototaro publication. The features of claim 15, which depends from claim 1, are taught by the Moatti-Sirat publication. One of skill in the art would understand how to modify the teachings of the Kusano publication and the Mastrototaro publication, in view of the Moatti-Sirat publication, to meet the features of claim 15. As such, claim 15 would be obvious under 35 U.S.C. § 103.

> Claim 15. The device of claim 1, wherein at least 95% of glucose concentration values measured by the device are within 25% of corresponding values determined by analysis of blood over the period of time.

The Moatti-Sirat publication teaches a glucose sensor for implantation in the subcutaneous tissue of an animal. See the Moatti-Sirat publication, Summary, pg. 224. The Moatti-Sirat publication teaches a membrane disposed over the glucose sensor. See the Moatti-Sirat publication, pg. 225. Further, page 225 and Table 1 of the Moatti-Sirat publication teaches that the electrode is configured to measure a current produced by the electrode with substantial linearity up to a glucose concentration of 22 mM (i.e., 400 mg/dL).

With regard to the claimed accuracy of the device of claim 15, The Moatti-Sirat publication uses the EGA of the Clark publication to present its experimental results. The experimental results of the Moatti-Sirat publication, in turn, fall within the accuracy standard called for in claim 15 of the Shults '562 patent. For example, the Moatti-Sirat publication teaches that subcutaneous glucose concentrations determined by an implanted sensor are correlated with "reference blood glucose" obtained from a tail vein sample. See the Moatti-Sirat publication, page 225. The correlation between the glucose concentration values measured by the device and the reference sensor is depicted in FIG. 6 (reproduced below) and described on page 227.

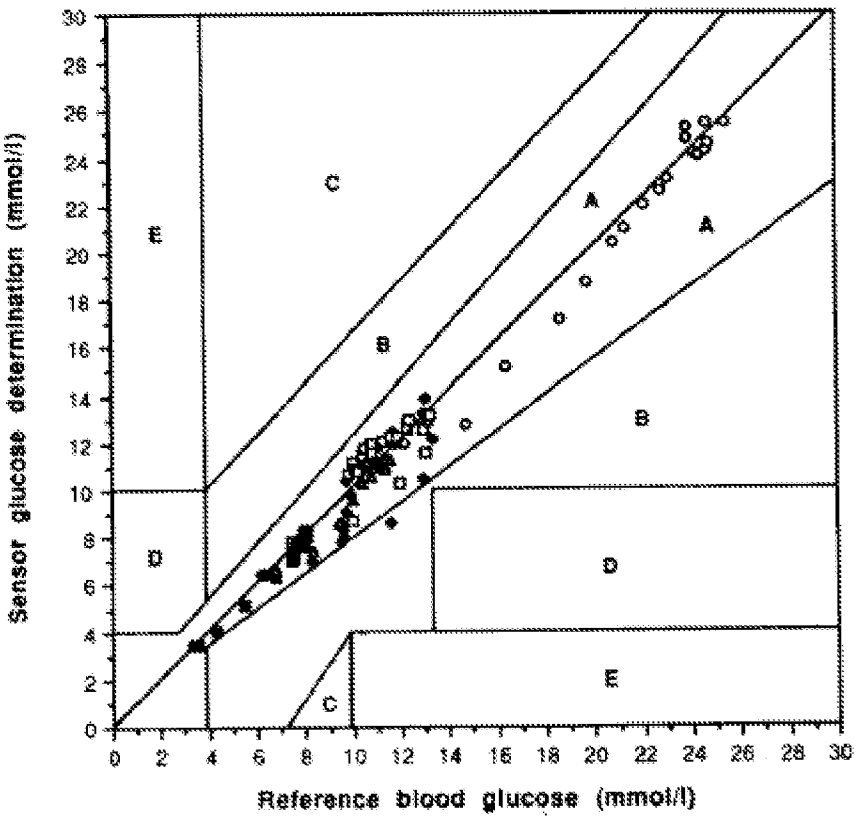

Fig. 6. Error grid analysis for estimation of the accuracy of sensor generated blood glucose values, ten days after implantation

As shown in FIG. 6, and described on page 227, 100 of 101 (i.e., 99%) of the experimental values fall within Zone A, which deviates no more than 20% from the reference. In other words, 99% of glucose concentration values measured by the signal are within 20% of one or more reference values. As such, the sensor/membrane combination described and tested in the Moatti-Sirat publication meets the claimed accuracy standard of "at least 95% of glucose concentration values measured by the device are within 25% of corresponding values determined by analysis of blood over the period of time."

Accordingly, one of skill in the art would understand how to modify the sensor of the Kusano publication and the Mastrototaro publication by including the sensor/membrane combination described and tested in the Moatti-Sirat publication and arrive at the features of claim 15. Such a modification of the Kusano publication and the Mastrototaro publication would simply be a combination of prior art elements according to their established functions, as noted above, and would be within the capabilities of a person having ordinary skill in the art.

2. Dependent Claim 20

As outlined above, claim 1 is rendered obvious by the combination of the Kusano publication and the Mastrototaro publication. The features of claim 20, which depends from claim 1, are taught by the Moatti-Sirat publication. One of skill in the art would understand how to modify the teachings of the Kusano publication and the Mastrototaro publication, in view of the Moatti-Sirat publication, to meet the features of claim 20. As such, claim 20 would be obvious under 35 U.S.C. § 103.

> Claim 20. The device of claim 1, wherein the period of time is at least about 3 days.

The Moatti-Sirat publication teaches a device (e.g., miniaturized glucose sensor) comprising electrodes configured for implantation in a subcutaneous tissue of the host for at least 10 days. See, for example, the Moatti-Sirat publication, Summary, and pgs. 224 and 228.

3. Dependent Claim 21

As outlined above, claim 1 is rendered obvious by the combination of the Kusano publication and the Mastrototaro publication. The features of claim 21, which depends from claim 1, are taught by the Moatti-Sirat publication. One of skill in the art would understand how to modify the teachings of the Kusano publication and the Mastrototaro publication, in view of the Moatti-Sirat publication, to meet the features of claim 21. As such, claim 21 would be obvious under 35 U.S.C. § 103.

> Claim 21. The device of claim 1, wherein the period of time is at least about 5 days.

The Moatti-Sirat publication teaches a device (e.g., miniaturized glucose sensor) comprising electrodes configured for implantation in a subcutaneous tissue of the host for at least 10 days. See, for example, the Moatti-Sirat publication, Summary, and pgs. 224 and 228.

4. Dependent Claim 22

As outlined above, claim 1 is rendered obvious by the combination of the Kusano publication and the Mastrototaro publication. The features of claim 22, which depends from claim 1, are taught by the Moatti-Sirat publication. One of skill in the art would understand how to modify the teachings of the Kusano publication and the Mastrototaro publication, in view of

the Moatti-Sirat publication, to meet the features of claim 22. As such, claim 22 would be obvious under 35 U.S.C. § 103.

> Claim 22. The device of claim 1, wherein the period of time is at least about 7 days.

The Moatti-Sirat publication teaches a device (e.g., miniaturized glucose sensor) comprising electrodes configured for implantation in a subcutaneous tissue of the host for at least 10 days. See, for example, the Moatti-Sirat publication, Summary, and pgs. 224 and 228.

F. Claim 25 is obvious under 35 U.S.C. § 103 in view of the Kusano publication, the Mastrototaro publication, and the Csöregi publication.

Claim 25 is unpatentable under 35 U.S.C. § 103(a) over the Kusano publication in view of the Mastrototaro publication, and further in view of the Csöregi publication. For the examiner's convenience, the arguments presented herein are summarized in the table provided in **Exhibit M**.

1. Dependent Claim 25

As outlined above, claim 1 is rendered obvious by the combination of the Kusano publication and the Mastrototaro publication. The features of claim 25, which depends from claim 1, are taught by the Csöregi publication. One of skill in the art would understand how to modify the teachings of the Kusano publication and the Mastrototaro publication, in view of the Csöregi publication, to meet the features of claim 25. As such, claim 25 would be obvious under 35 U.S.C. § 103.

> Claim 25. The device of claim 1, wherein the device is configured for single-point recalibration.

The Csöregi publication teaches a device for measuring glucose concentration in a host. See the Csöregi publication, Abstract. The sensors of the Csöregi publication are configured for single-point recalibration. Specifically, the Csöregi publication states:

> The stability observed and the existence of a valid zero point in the presence of interferants suggested that the sensor could be used in vivo for 72 h and be tested/recalibrated in vivo through a single-point calibration, i.e., by withdrawing only a single sample of blood for independent analysis.

The Csöregi publication, pg. 3136.

Accordingly, one of skill in the art would understand how to modify the sensor of the Kusano publication and the Mastrototaro publication by configuring the sensor for single point recalibration as described in the Csöregi publication and arrive at the features of claim 25. Such a modification of the Allen '063 patent would simply be a combination of prior art elements according to their established functions, as noted above, and would be within the capabilities of a person having ordinary skill in the art.

G. Claims 28, 32, 36, 53, 57, 61, 78-80, 84, 88, 105-107, 111, 131, and 132 are anticipated under 35 U.S.C. § 102 by the Kusano publication.

Claims 28, 32, 36, 53, 57, 61, 78-80, 84, 88, 105-107, 111, 131, and 132 are anticipated under 35 U.S.C. § 102 by the Kusano publication. Sections VI.G.1 – VI.G.17 detail how claims 28, 32, 36, 53, 57, 61, 78-80, 84, 88, 105-107, 111, 131, and 132 are anticipated by the Kusano publication. For the examiner's convenience, the arguments presented herein are summarized in the table provided in **Exhibit N**.

1. Independent Claim 28

> Claim 28. A device for measuring a glucose concentration in a host, the device comprising:
>
> *Part of Claim 28*

The Kusano publication teaches a device for measuring glucose concentration in a host. See the Kusano publication, Abstract.

> an electrode surface operably connected to an electronic circuit and configured to continuously measure a signal indicative of a glucose concentration in a host for a period of time; and
>
> *Part of Claim 28*

The Kusano publication teaches an electrode surface operably connected to an electronic circuit and configured to continuously measure a signal indicative of a glucose concentration in a host for a period of time. See the Kusano publication, Abstract; pgs. 2-3; and Figure 2 (reproduced below).

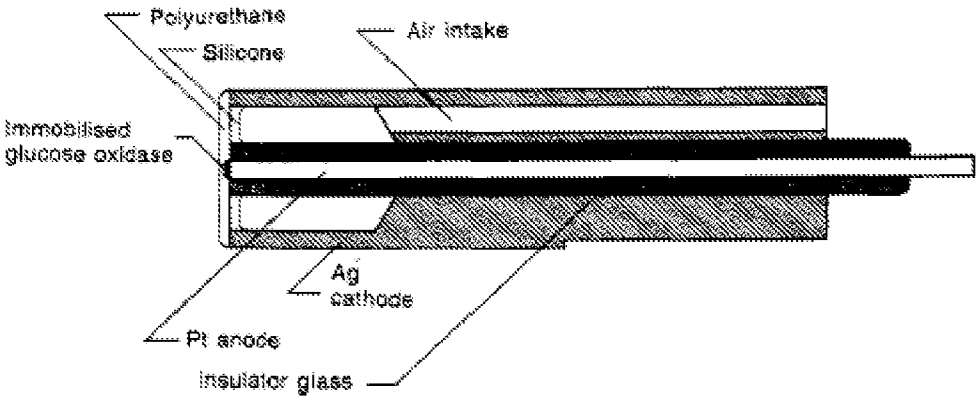

Figure 2. Schematic diagram of the experimental glucose electrode.

> a membrane located over at least a portion of the electrode surface, the membrane comprising a layer configured to control a flux of oxygen and glucose;
>
> *Part of Claim 28*

The Kusano publication teaches a membrane located over at least a portion of the electrode surface, the membrane comprising a layer configured to control a flux of oxygen and glucose. See the Kusano publication, Abstract; pgs. 2-3; and Figure 2 (above).

> wherein the device is capable of exhibiting, at a glucose concentration of 400 mg/dL, no more than a 10% drop in sensor output over a range of pO_2 from 150 mm Hg down to 30 mm Hg;
>
> *Part of Claim 28*

The Kusano publication teaches a device is capable of exhibiting, at a glucose concentration of 400 mg/dL, no more than a 10% drop in sensor output over a range of pO_2 from 150 mmHg down to 30 mmHg. See the Kusano publication, section 3.4, pgs. 6-7; Figure 8; and Conclusion.

Specifically, the Kusano publication presents a sensor system that measures glucose concentrations from 0 to 500 mg/dL, in a fluid with an oxygen concentration ranging from 0 kPa (0 mmHg) to 20.5 kPa (154 mmHg). See the Kusano publication, pgs. 6-7, and Figure 8. As such, the ranges disclosed in the Kusano publication encompasses the ranges claimed in the Shults '562 patent.

The Kusano publication further states:

> The electrode calibration curve is shown in figure 8. Reproducibility at a glucose concentration of 500 mg dl^{-1} (27.8 mmol l^{-1}) was within an error of ± 3%. ***Oxygen concentration had no effect on electrode response***.

The Kusano publication, pgs. 6-7 (emphasis added).

Figure 8 of the Kusano publication (reproduced below) shows a linear current measurement up to 500 mg/dL, and a negligible drop in sensor output (i.e., "an error of ± 3%") as the pO_2 is varied from 0 kPa (0 mmHg) to 20.5 kPa (154 mmHg).

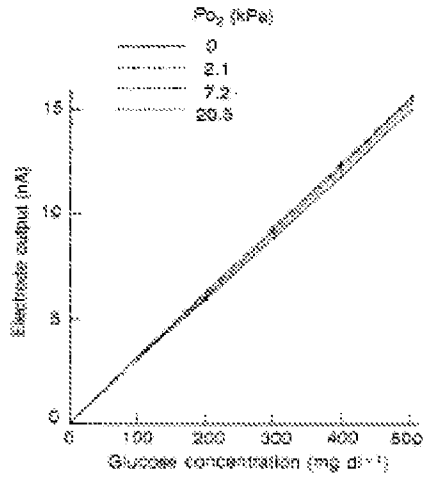

Figure 8. Electrode calibration curves under various Po_2.

The concluding remarks of the Kusano publication further state:

> Glucose concentrations of 0 to 500 mg dl^{-1} (27.8 mmol l^{-1}) could be measured without being affected by oxygen concentration in the range of 0 to 163 mmHg (21.7 kPa).

The Kusano publication, pg. 8.

and wherein the device is configured to be implanted in the host.
Part of Claim 28

While the sensors of the Kusano publication are tested *in vitro*, they are designed and intended for *in vivo* implantation. See the Kusano publication, Abstract. As such, the Kusano publication teaches a device configure to be implanted in the host.

2. Dependent Claim 32

In addition to showing each and every feature of claim 28, the Kusano publication discloses the features of claim 32, which depends from claim 28. Claim 32 is therefore anticipated, under 35 U.S.C. § 102, by the Kusano publication.

> Claim 32. The device of claim 28, wherein the membrane comprises a layer comprising an enzyme.

The membrane disclosed in the Kusano publication includes an enzyme layer of immobilized glucose oxidase. See the Kusano publication, pg. 3; and Figure 2 (above).

3. Dependent Claim 36

In addition to showing each and every feature of claim 28, the Kusano publication discloses the features of claim 36, which depends from claim 28. Claim 36 is therefore anticipated, under 35 U.S.C. § 102, by the Kusano publication.

> Claim 36. The device of claim 28, wherein the membrane comprises a urethane polymer or a polyurethane.

The Kusano publication teaches forming the membrane of a polyurethane. See the Kusano publication, pg. 3; and Figure 2 (above).

4. Independent Claim 53

> Claim 53. A device for measuring a glucose concentration in a host, the device comprising:
>
> *Part of Claim 53*

The Kusano publication teaches a device for measuring glucose concentration in a host. See the Kusano publication, Abstract.

> a sensor operably connected to an electronic circuit and configured to continuously measure a signal indicative of a glucose concentration in a host for a period of time; and
>
> *Part of Claim 53*

The Kusano publication teaches a sensor operably connected to an electronic circuit and configured to continuously measure a signal indicative of a glucose concentration in a host for a period of time. See the Kusano publication, Abstract; pgs. 2-3; and Figure 2 (reproduced below).

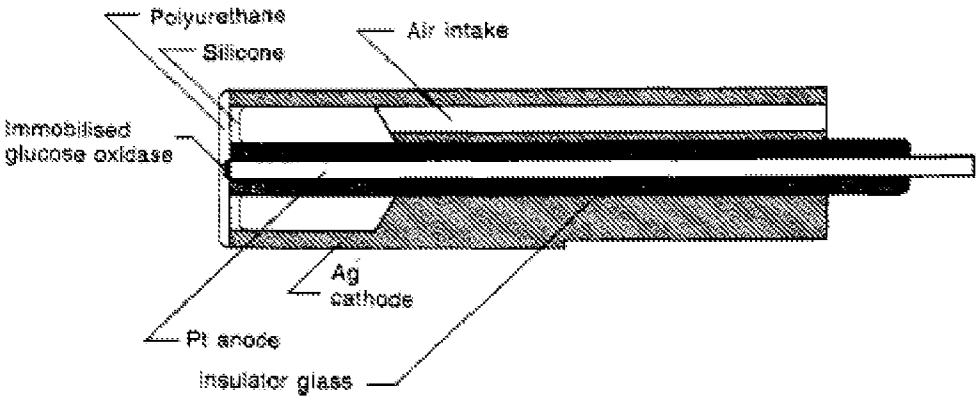

Figure 2. Schematic diagram of the experimental glucose electrode.

> a membrane located over at least a portion of the sensor, the membrane comprising a layer configured to control a flux of oxygen and glucose;
>
> *Part of Claim 53*

The Kusano publication teaches a membrane located over at least a portion of the electrode surface, the membrane comprising a layer configured to control a flux of oxygen and glucose. See the Kusano publication, Abstract; pgs. 2-3; and Figure 2 (above).

> wherein the device is capable of exhibiting, at a glucose concentration of 400 mg/dL, no more than a 10% drop in sensor output over a range of pO_2 from 150 mm Hg down to 30 mm Hg;
>
> *Part of Claim 53*

The Kusano publication teaches a device is capable of exhibiting, at a glucose concentration of 400 mg/dL, no more than a 10% drop in sensor output over a range of pO_2 from 150 mmHg down to 30 mmHg. See the Kusano publication, section 3.4, pgs. 6-7; Figure 8; and Conclusion.

Specifically, the Kusano publication presents a sensor system that measures glucose concentrations from 0 to 500 mg/dL, in a fluid with an oxygen concentration ranging from 0 kPa (0 mmHg) to 20.5 kPa (154 mmHg). See the Kusano publication, pgs. 6-7, and Figure 8. As such, the ranges disclosed in the Kusano publication encompasses the ranges claimed in the Shults '562 patent.

The Kusano publication further states:

> The electrode calibration curve is shown in figure 8. Reproducibility at a glucose concentration of 500 mg dl^{-1} (27.8 mmol l^{-1}) was within an error of ± 3%. ***Oxygen concentration had no effect on electrode response***.

The Kusano publication, pgs. 6-7 (emphasis added).

Figure 8 of the Kusano publication (reproduced below) shows a linear current measurement up to 500 mg/dL, and a negligible drop in sensor output (i.e., "an error of ± 3%") as the pO_2 is varied from 0 kPa (0 mmHg) to 20.5 kPa (154 mmHg).

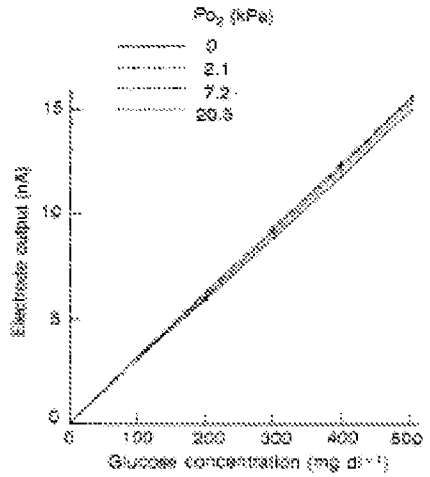

Figure 8. Electrode calibration curves under various Po_2.

The concluding remarks of the Kusano publication further state:

> Glucose concentrations of 0 to 500 mg dl^{-1} (27.8 mmol l^{-1}) could be measured without being affected by oxygen concentration in the range of 0 to 163 mmHg (21.7 kPa).

The Kusano publication, pg. 8.

> and wherein the device is configured to respond substantially linearly to changes in glucose concentration at a glucose concentration of up to at least 400 mg/dL.
>
> *Part of Claim 53*

As shown in Figure 8 above, the sensor of the Kusano publication responds substantially linearly to changes in glucose concentration at a glucose concentration of up to at least 400 mg/dL.

5. Dependent Claim 57

In addition to showing each and every feature of claim 53, the Kusano publication discloses the features of claim 57, which depends from claim 53. Claim 57 is therefore anticipated, under 35 U.S.C. § 102, by the Kusano publication.

> Claim 57. The device of claim 53, wherein the membrane comprises a layer comprising an enzyme.

The membrane disclosed in the Kusano publication includes an enzyme layer of immobilized glucose oxidase. See the Kusano publication, pg. 3; and Figure 2 (above).

6. Dependent Claim 61

In addition to showing each and every feature of claim 53, the Kusano publication discloses the features of claim 61, which depends from claim 53. Claim 61 is therefore anticipated, under 35 U.S.C. § 102, by the Kusano publication.

> Claim 61. The device of claim 53, wherein the membrane comprises a urethane polymer or a polyurethane.

The Kusano publication teaches forming the membrane of a polyurethane. See the Kusano publication, pg. 3; and Figure 2 (above).

7. Dependent Claim 78

In addition to showing each and every feature of claim 53, the Kusano publication discloses the features of claim 78, which depends from claim 53. Claim 78 is therefore anticipated, under 35 U.S.C. § 102, by the Kusano publication.

> Claim 78. The device of claim 53, wherein the device is configured to be implanted in the host.

While the sensors of the Kusano publication are tested *in vitro*, they are designed and intended for *in vivo* implantation. See the Kusano publication, Abstract. As such, the Kusano publication teaches a device configure to be implanted in the host.

8. Dependent Claim 79

In addition to showing each and every feature of claim 53, the Kusano publication discloses the features of claim 79, which depends from claim 53. Claim 79 is therefore anticipated, under 35 U.S.C. § 102, by the Kusano publication.

> Claim 79. The device of claim 53, wherein the device is configured to respond substantially linearly to changes in glucose concentration at a glucose concentration of up to at least 400 mg/dL.

As shown in Figure 8 above, the sensor of the Kusano publication responds substantially linearly to changes in glucose concentration at a glucose concentration of up to at least 400 mg/dL.

9. Independent Claim 80

> Claim 80. A device for measuring a glucose concentration in a host, the device comprising:
>
> *Part of Claim 80*

The Kusano publication teaches a device for measuring glucose concentration in a host. See the Kusano publication, Abstract.

> a sensor operably connected to an electronic circuit and configured to continuously measure a signal indicative of a glucose concentration in a host for a period of time; and
>
> *Part of Claim 80*

The Kusano publication teaches a sensor operably connected to an electronic circuit and configured to continuously measure a signal indicative of a glucose concentration in a host for a period of time. See the Kusano publication, Abstract; pgs. 2-3; and Figure 2 (reproduced below).

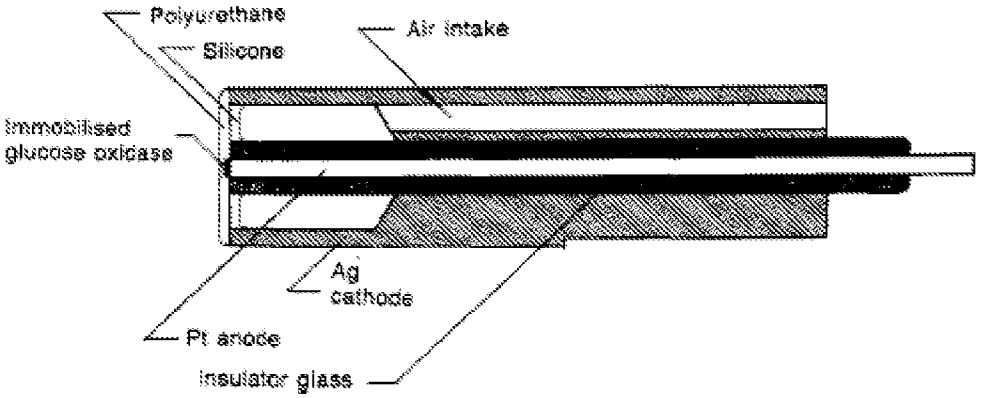

Figure 2. Schematic diagram of the experimental glucose electrode.

> a membrane located over at least a portion of the sensor, the membrane comprising a layer configured to control a flux of oxygen and glucose;
>
> *Part of Claim 80*

The Kusano publication teaches a membrane located over at least a portion of the electrode surface, the membrane comprising a layer configured to control a flux of oxygen and glucose. See the Kusano publication, Abstract; pgs. 2-3; and Figure 2 (above).

> wherein the device is capable of exhibiting, at a glucose concentration of 400 mg/dL, no more than a 10% drop in sensor output over a range of pO_2 from 150 mm Hg down to 30 mm Hg;
>
> *Part of Claim 80*

The Kusano publication teaches a device is capable of exhibiting, at a glucose concentration of 400 mg/dL, no more than a 10% drop in sensor output over a range of pO_2 from 150 mmHg down to 30 mmHg. See the Kusano publication, section 3.4, pgs. 6-7; Figure 8; and Conclusion.

Specifically, the Kusano publication presents a sensor system that measures glucose concentrations from 0 to 500 mg/dL, in a fluid with an oxygen concentration ranging from 0 kPa (0 mmHg) to 20.5 kPa (154 mmHg). See the Kusano publication, pgs. 6-7, and Figure 8. As such, the ranges disclosed in the Kusano publication encompasses the ranges claimed in the Shults '562 patent.

The Kusano publication further states:

> The electrode calibration curve is shown in figure 8. Reproducibility at a glucose concentration of 500 mg dl^{-1} (27.8 mmol l^{-1}) was within an error of ± 3%. ***Oxygen concentration had no effect on electrode response***.

The Kusano publication, pgs. 6-7 (emphasis added).

Figure 8 of the Kusano publication (reproduced below) shows a linear current measurement up to 500 mg/dL, and a negligible drop in sensor output (i.e., "an error of ± 3%") as the pO_2 is varied from 0 kPa (0 mmHg) to 20.5 kPa (154 mmHg).

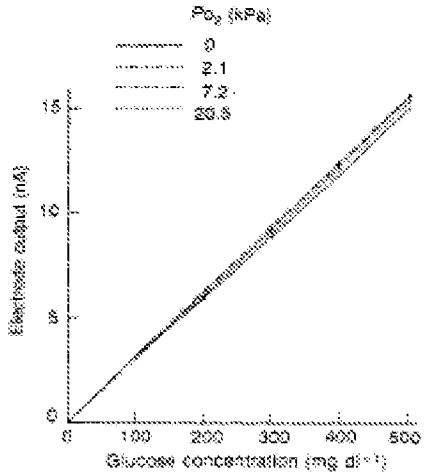

Figure 8. Electrode calibration curves under various Po_2.

The concluding remarks of the Kusano publication further state:

> Glucose concentrations of 0 to 500 mg dl^{-1} (27.8 mmol l^{-1}) could be measured without being affected by oxygen concentration in the range of 0 to 163 mmHg (21.7 kPa).

The Kusano publication, pg. 8.

> and wherein the device is capable of attaining a 90% time response to a 100 mg/dL glucose concentration step in less than 5 minutes.
>
> *Part of Claim 80*

The Kusano publication teaches a device capable of attaining a 90% time response to a 100 mg/dL glucose concentration step in less than five minutes. See the Kusano publication, pg. 7, and Figure 9. More specifically, the Kusano publication states:

> Figure 9 shows electrode output over a 24 h period at a glucose concentration of 100 mg dl^{-1} (5.55 mmol l^{-1}) and a $pO_2 = 0$ mmHg. … The fluctuation of the electrode output was within ± 5%.

Id.

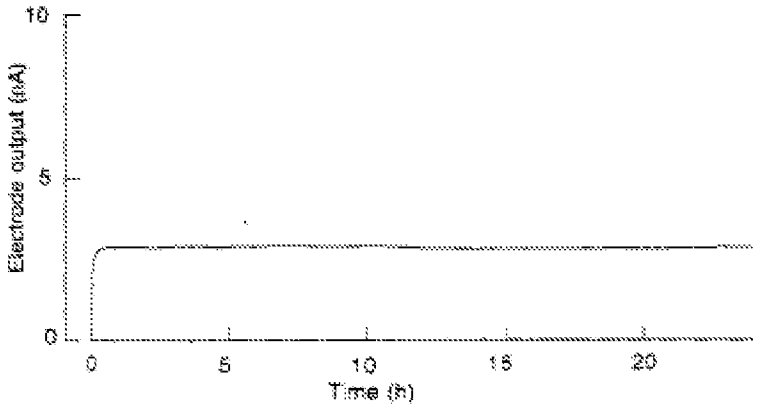

Figure 9. An example of observation of long-term stability of the electrode (glucose concentration = 100 mg dl^{-1}, Po_2 = 0 mmHg, immobilised GOD = 0.5 μg, polyurethane concentration = 6%).

10. Dependent Claim 84

In addition to showing each and every feature of claim 80, the Kusano publication discloses the features of claim 84, which depends from claim 80. Claim 84 is therefore anticipated, under 35 U.S.C. § 102, by the Kusano publication.

> Claim 84. The device of claim 80, wherein the membrane comprises a layer comprising an enzyme.

The membrane disclosed in the Kusano publication includes an enzyme layer of immobilized glucose oxidase. See the Kusano publication, pg. 3; and Figure 2 (above).

11. Dependent Claim 88

In addition to showing each and every feature of claim 80, the Kusano publication discloses the features of claim 88, which depends from claim 80. Claim 88 is therefore anticipated, under 35 U.S.C. § 102, by the Kusano publication.

> Claim 88. The device of claim 80, wherein the membrane comprises a urethane polymer or a polyurethane.

The Kusano publication teaches forming the membrane of a polyurethane. See the Kusano publication, pg. 3; and Figure 2 (above).

12. Dependent Claim 105

In addition to showing each and every feature of claim 80, the Kusano publication discloses the features of claim 105, which depends from claim 80. Claim 105 is therefore anticipated, under 35 U.S.C. § 102, by the Kusano publication.

> Claim 105. The device of claim 80, wherein the device is configured to be implanted in the host.

While the sensors of the Kusano publication are tested *in vitro*, they are designed and intended for *in vivo* implantation. See the Kusano publication, Abstract. As such, the Kusano publication teaches a device configure to be implanted in the host.

13. Dependent Claim 106

In addition to showing each and every feature of claim 80, the Kusano publication discloses the features of claim 106, which depends from claim 80. Claim 106 is therefore anticipated, under 35 U.S.C. § 102, by the Kusano publication.

> Claim 106. The device of claim 80, wherein the device is configured to respond substantially linearly to changes in glucose concentration at a glucose concentration of up to at least 400 mg/dL.

As shown in Figure 8 above, the sensor of the Kusano publication responds substantially linearly to changes in glucose concentration at a glucose concentration of up to at least 400 mg/dL.

14. Independent Claim 107

> Claim 107. A device for measuring a glucose concentration in a host, the device comprising:
>
> *Part of Claim 107*

The Kusano publication teaches a device for measuring glucose concentration in a host. See the Kusano publication, Abstract.

> a sensor operably connected to an electronic circuit and configured to continuously measure a signal indicative of a glucose concentration in a host for a period of time; and
>
> *Part of Claim 107*

The Kusano publication teaches a sensor operably connected to an electronic circuit and configured to continuously measure a signal indicative of a glucose concentration in a host for a period of time. See the Kusano publication, Abstract; pgs. 2-3; and Figure 2 (reproduced below).

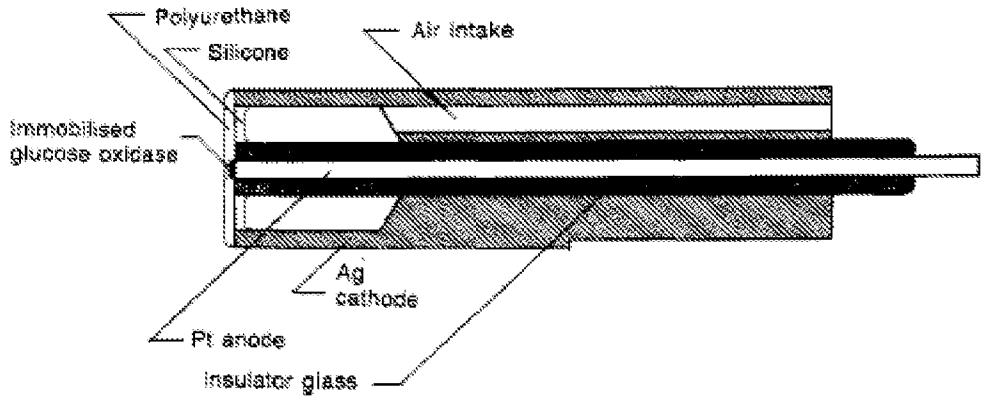

Figure 2. Schematic diagram of the experimental glucose electrode.

> a membrane located over at least a portion of the sensor, wherein the membrane comprises a layer configured to control a flux of oxygen and glucose,
>
> *Part of Claim 107*

The Kusano publication teaches a membrane located over at least a portion of the electrode surface, the membrane comprising a layer configured to control a flux of oxygen and glucose. See the Kusano publication, Abstract; pgs. 2-3; and Figure 2 (above).

> wherein the layer comprises a polyurethane or urethane polymer; wherein the device is capable of exhibiting, at a glucose concentration of 400 mg/dL, no more than a 10% drop in sensor output over a range of pO_2 from 150 mm Hg down to 30 mm Hg.
>
> *Part of Claim 107*

The Kusano publication teaches a device is capable of exhibiting, at a glucose concentration of 400 mg/dL, no more than a 10% drop in sensor output over a range of pO_2 from 150 mmHg down to 30 mmHg. See the Kusano publication, section 3.4, pgs. 6-7; Figure 8; and Conclusion.

Specifically, the Kusano publication presents a sensor system that measures glucose concentrations from 0 to 500 mg/dL, in a fluid with an oxygen concentration ranging from 0 kPa (0 mmHg) to 20.5 kPa (154 mmHg). See the Kusano publication, pgs. 6-7, and Figure 8. As such, the ranges disclosed in the Kusano publication encompasses the ranges claimed in the Shults '562 patent.

The Kusano publication further states:

> The electrode calibration curve is shown in figure 8. Reproducibility at a glucose concentration of 500 mg dl^{-1} (27.8 mmol l^{-1}) was within an error of ± 3%. ***Oxygen concentration had no effect on electrode response***.

The Kusano publication, pgs. 6-7 (emphasis added).

Figure 8 of the Kusano publication (reproduced below) shows a linear current measurement up to 500 mg/dL, and a negligible drop in sensor output (i.e., "an error of ± 3%") as the pO_2 is varied from 0 kPa (0 mmHg) to 20.5 kPa (154 mmHg).

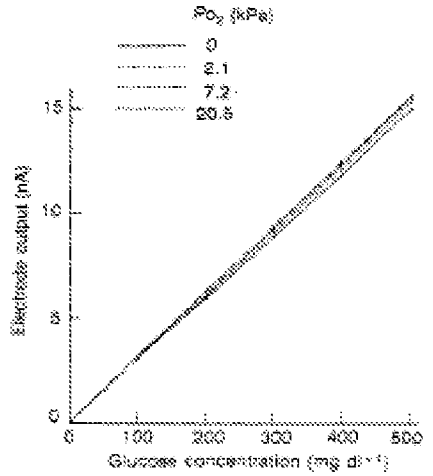

Figure 8. Electrode calibration curves under various Po_2.

The concluding remarks of the Kusano publication further state:

> Glucose concentrations of 0 to 500 mg dl^{-1} (27.8 mmol l^{-1}) could be measured without being affected by oxygen concentration in the range of 0 to 163 mmHg (21.7 kPa).

The Kusano publication, pg. 8.

15. Dependent Claim 111

In addition to showing each and every feature of claim 107, the Kusano publication discloses the features of claim 111, which depends from claim 107. Claim 111 is therefore anticipated, under 35 U.S.C. § 102, by the Kusano publication.

> Claim 111. The device of claim 107, wherein the membrane comprises a layer comprising an enzyme.

The membrane disclosed in the Kusano publication includes an enzyme layer of immobilized glucose oxidase. See the Kusano publication, pg. 3; and Figure 2 (above).

16. Dependent Claim 131

In addition to showing each and every feature of claim 107, the Kusano publication discloses the features of claim 131, which depends from claim 107. Claim 131 is therefore anticipated, under 35 U.S.C. § 102, by the Kusano publication.

> Claim 131. The device of claim 107, wherein the device is configured to be implanted in the host.

While the sensors of the Kusano publication are tested *in vitro*, they are designed and intended for *in vivo* implantation. See the Kusano publication, Abstract. As such, the Kusano publication teaches a device configure to be implanted in the host.

17. Dependent Claim 132

In addition to showing each and every feature of claim 107, the Kusano publication discloses the features of claim 132, which depends from claim 107. Claim 132 is therefore anticipated, under 35 U.S.C. § 102, by the Kusano publication.

> Claim 132. The device of claim 107, wherein the device is configured to respond substantially linearly to changes in glucose concentration at a glucose concentration of up to at least 400 mg/dL.

As shown in Figure 8 above, the sensor of the Kusano publication responds substantially linearly to changes in glucose concentration at a glucose concentration of up to at least 400 mg/dL.

H. Claims 42, 47-49, 67, 72-74, 94, 99-101, 120, and 125-127 are obvious under 35 U.S.C. § 103 in view of the Kusano publication and the Moatti-Sirat publication.

Claims 42, 47-49, 67, 72-74, 94, 99-101, 120, and 125-127 are unpatentable under 35 U.S.C. § 103(a) over the Kusano publication in view of the Moatti-Sirat publication. Sections VI.H.1 – VI.H.16 detail how claims 42, 47-49, 67, 72-74, 94, 99-101, 120, and 125-127 are rendered obvious by the combination of the Kusano publication and the Moatti-Sirat publication. For the examiner's convenience, the arguments presented herein are summarized in the table provided in **Exhibit O**.

1. Dependent Claim 42

As outlined above, claim 28 is anticipated by the Kusano publication. The features of claim 42, which depends from claim 28, are taught by the Moatti-Sirat publication. One of skill in the art would understand how to modify the teachings of the Kusano publication, in view of the Moatti-Sirat publication, to meet the features of claim 42. As such, claim 42 would be obvious under 35 U.S.C. § 103.

> Claim 42. The device of claim 28, wherein at least 95% of glucose concentration values measured by the device are within 25% of corresponding values determined by analysis of blood over the period of time.

The Moatti-Sirat publication teaches a glucose sensor for implantation in the subcutaneous tissue of an animal. See the Moatti-Sirat publication, Summary, pg. 224. The Moatti-Sirat publication teaches a membrane disposed over the glucose sensor. See the Moatti-Sirat publication, pg. 225. Further, page 225 and Table 1 of the Moatti-Sirat publication teaches that the electrode is configured to measure a current produced by the electrode with substantial linearity up to a glucose concentration of 22 mM (i.e., 400 mg/dL).

With regard to the claimed accuracy of the device of claim 42, The Moatti-Sirat publication uses the EGA of the Clark publication to present its experimental results. The experimental results of the Moatti-Sirat publication, in turn, fall within the accuracy standard called for in claim 42. For example, the Moatti-Sirat publication teaches that subcutaneous glucose concentrations determined by an implanted sensor are correlated with "reference blood glucose" obtained from a tail vein sample. See the Moatti-Sirat publication, page 225. The

correlation between the glucose concentration values measured by the device and the reference sensor is depicted in FIG. 6 (reproduced below) and described on page 227.

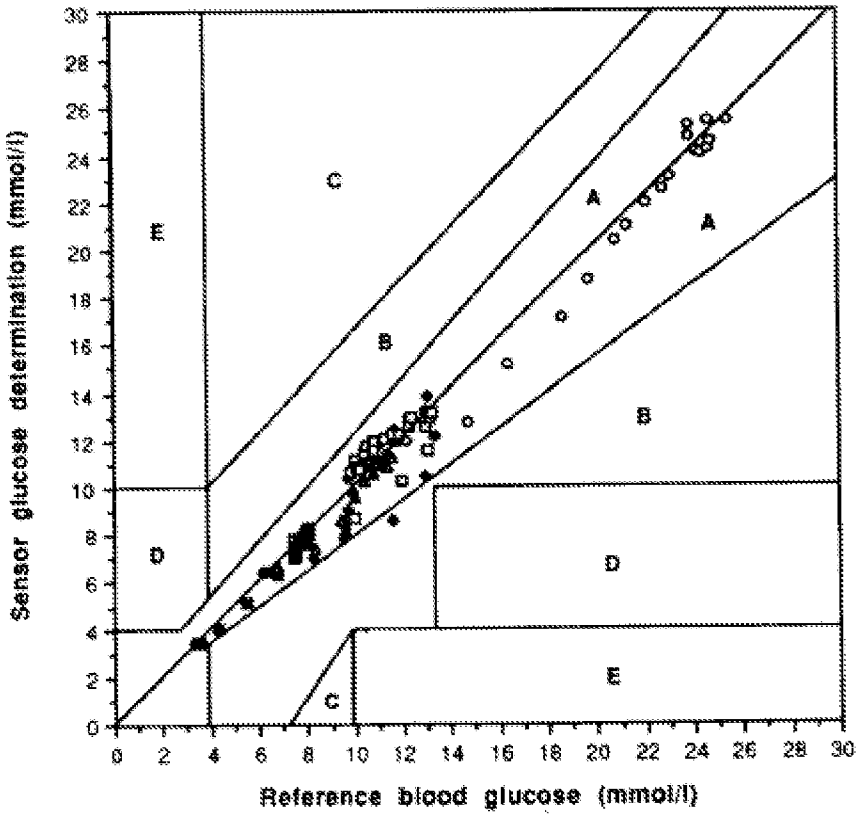

Fig.6. Error grid analysis for estimation of the accuracy of sensor generated blood glucose values, ten days after implantation

As shown in FIG. 6, and described on page 227, 100 of 101 (i.e., 99%) of the experimental values fall within Zone A, which deviates no more than 20% from the reference. In other words, 99% of glucose concentration values measured by the signal are within 20% of one or more reference values. As such, the sensor/membrane combination described and tested in the Moatti-Sirat publication meets the claimed accuracy standard of "at least 95% of glucose concentration values measured by the device are within 25% of corresponding values determined by analysis of blood over the period of time."

Accordingly, one of skill in the art would understand how to modify the sensor of the Kusano publication by including the sensor/membrane combination described and tested in the Moatti-Sirat publication and arrive at the features of claim 42. Such a modification of the Kusano publication would simply be a combination of prior art elements according to their

established functions, as noted above, and would be within the capabilities of a person having ordinary skill in the art.

2. Dependent Claim 47

As outlined above, claim 28 is anticipated by the Kusano publication. The features of claim 47, which depends from claim 28, are taught by the Moatti-Sirat publication. One of skill in the art would understand how to modify the teachings of the Kusano publication, in view of the Moatti-Sirat publication, to meet the features of claim 47. As such, claim 47 would be obvious under 35 U.S.C. § 103.

> Claim 47. The device of claim 28, wherein the period of time is at least about 3 days.

The Moatti-Sirat publication teaches a device (e.g., miniaturized glucose sensor) comprising electrodes configured for implantation in a subcutaneous tissue of the host for at least 10 days. See, for example, the Moatti-Sirat publication, Summary, and pgs. 224 and 228.

3. Dependent Claim 48

As outlined above, claim 28 is anticipated by the Kusano publication. The features of claim 48, which depends from claim 28, are taught by the Moatti-Sirat publication. One of skill in the art would understand how to modify the teachings of the Kusano publication, in view of the Moatti-Sirat publication, to meet the features of claim 48. As such, claim 48 would be obvious under 35 U.S.C. § 103.

> Claim 48. The device of claim 28, wherein the period of time is at least about 5 days.

The Moatti-Sirat publication teaches a device (e.g., miniaturized glucose sensor) comprising electrodes configured for implantation in a subcutaneous tissue of the host for at least 10 days. See, for example, the Moatti-Sirat publication, Summary, and pgs. 224 and 228.

4. Dependent Claim 49

As outlined above, claim 28 is anticipated by the Kusano publication. The features of claim 49, which depends from claim 28, are taught by the Moatti-Sirat publication. One of skill in the art would understand how to modify the teachings of the Kusano publication, in view of

the Moatti-Sirat publication, to meet the features of claim 49. As such, claim 49 would be obvious under 35 U.S.C. § 103.

> Claim 49. The device of claim 28, wherein the period of time is at least about 7 days.

The Moatti-Sirat publication teaches a device (e.g., miniaturized glucose sensor) comprising electrodes configured for implantation in a subcutaneous tissue of the host for at least 10 days. See, for example, the Moatti-Sirat publication, Summary, and pgs. 224 and 228.

5. Dependent Claim 67

As outlined above, claim 53 is anticipated by the Kusano publication. The features of claim 67, which depends from claim 53, are taught by the Moatti-Sirat publication. One of skill in the art would understand how to modify the teachings of the Kusano publication, in view of the Moatti-Sirat publication, to meet the features of claim 67. As such, claim 67 would be obvious under 35 U.S.C. § 103.

> Claim 67. The device of claim 53, wherein at least 95% of glucose concentration values measured by the device are within 25% of corresponding values determined by analysis of blood over the period of time.

The Moatti-Sirat publication teaches a glucose sensor for implantation in the subcutaneous tissue of an animal. See the Moatti-Sirat publication, Summary, pg. 224. The Moatti-Sirat publication teaches a membrane disposed over the glucose sensor. See the Moatti-Sirat publication, pg. 225. Further, page 225 and Table 1 of the Moatti-Sirat publication teaches that the electrode is configured to measure a current produced by the electrode with substantial linearity up to a glucose concentration of 22 mM (i.e., 400 mg/dL).

With regard to the claimed accuracy of the device of claim 67, The Moatti-Sirat publication uses the EGA of the Clark publication to present its experimental results. The experimental results of the Moatti-Sirat publication, in turn, fall within the accuracy standard called for in claim 67. For example, the Moatti-Sirat publication teaches that subcutaneous glucose concentrations determined by an implanted sensor are correlated with "reference blood glucose" obtained from a tail vein sample. See the Moatti-Sirat publication, page 225. The correlation between the glucose concentration values measured by the device and the reference sensor is depicted in FIG. 6 (reproduced below) and described on page 227.

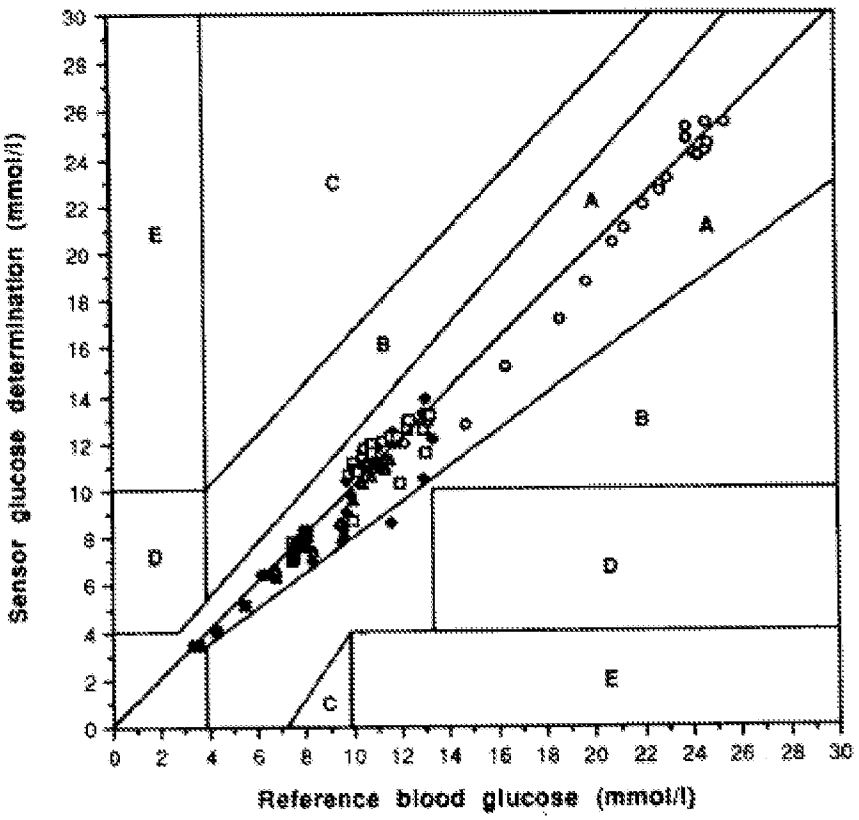

Fig. 6. Error grid analysis for estimation of the accuracy of sensor generated blood glucose values, ten days after implantation

As shown in FIG. 6, and described on page 227, 100 of 101 (i.e., 99%) of the experimental values fall within Zone A, which deviates no more than 20% from the reference. In other words, 99% of glucose concentration values measured by the signal are within 20% of one or more reference values. As such, the sensor/membrane combination described and tested in the Moatti-Sirat publication meets the claimed accuracy standard of "at least 95% of glucose concentration values measured by the device are within 25% of corresponding values determined by analysis of blood over the period of time."

Accordingly, one of skill in the art would understand how to modify the sensor of the Kusano publication by including the sensor/membrane combination described and tested in the Moatti-Sirat publication and arrive at the features of claim 67. Such a modification of the Kusano publication would simply be a combination of prior art elements according to their established functions, as noted above, and would be within the capabilities of a person having ordinary skill in the art.

6. Dependent Claim 72

As outlined above, claim 53 is anticipated by the Kusano publication. The features of claim 72, which depends from claim 53, are taught by the Moatti-Sirat publication. One of skill in the art would understand how to modify the teachings of the Kusano publication, in view of the Moatti-Sirat publication, to meet the features of claim 72. As such, claim 72 would be obvious under 35 U.S.C. § 103.

> Claim 72. The device of claim 53, wherein the period of time is at least about 3 days.

The Moatti-Sirat publication teaches a device (e.g., miniaturized glucose sensor) comprising electrodes configured for implantation in a subcutaneous tissue of the host for at least 10 days. See, for example, the Moatti-Sirat publication, Summary, and pgs. 224 and 228.

7. Dependent Claim 73

As outlined above, claim 53 is anticipated by the Kusano publication. The features of claim 73, which depends from claim 53, are taught by the Moatti-Sirat publication. One of skill in the art would understand how to modify the teachings of the Kusano publication, in view of the Moatti-Sirat publication, to meet the features of claim 73. As such, claim 73 would be obvious under 35 U.S.C. § 103.

> Claim 73. The device of claim 53, wherein the period of time is at least about 5 days.

The Moatti-Sirat publication teaches a device (e.g., miniaturized glucose sensor) comprising electrodes configured for implantation in a subcutaneous tissue of the host for at least 10 days. See, for example, the Moatti-Sirat publication, Summary, and pgs. 224 and 228.

8. Dependent Claim 74

As outlined above, claim 53 is anticipated by the Kusano publication. The features of claim 74, which depends from claim 53, are taught by the Moatti-Sirat publication. One of skill in the art would understand how to modify the teachings of the Kusano publication, in view of the Moatti-Sirat publication, to meet the features of claim 74. As such, claim 74 would be obvious under 35 U.S.C. § 103.

> Claim 74. The device of claim 53, wherein the period of time is at least about 7 days.

The Moatti-Sirat publication teaches a device (e.g., miniaturized glucose sensor) comprising electrodes configured for implantation in a subcutaneous tissue of the host for at least 10 days. See, for example, the Moatti-Sirat publication, Summary, and pgs. 224 and 228.

9. Dependent Claim 94

As outlined above, claim 80 is anticipated by the Kusano publication. The features of claim 94, which depends from claim 80, are taught by the Moatti-Sirat publication. One of skill in the art would understand how to modify the teachings of the Kusano publication, in view of the Moatti-Sirat publication, to meet the features of claim 94. As such, claim 94 would be obvious under 35 U.S.C. § 103.

> Claim 94. The device of claim 80, wherein at least 95% of glucose concentration values measured by the device are within 25% of corresponding values determined by analysis of blood over the period of time.

The Moatti-Sirat publication teaches a glucose sensor for implantation in the subcutaneous tissue of an animal. See the Moatti-Sirat publication, Summary, pg. 224. The Moatti-Sirat publication teaches a membrane disposed over the glucose sensor. See the Moatti-Sirat publication, pg. 225. Further, page 225 and Table 1 of the Moatti-Sirat publication teaches that the electrode is configured to measure a current produced by the electrode with substantial linearity up to a glucose concentration of 22 mM (i.e., 400 mg/dL).

With regard to the claimed accuracy of the device of claim 94, The Moatti-Sirat publication uses the EGA of the Clark publication to present its experimental results. The experimental results of the Moatti-Sirat publication, in turn, fall within the accuracy standard called for in claim 94. For example, the Moatti-Sirat publication teaches that subcutaneous glucose concentrations determined by an implanted sensor are correlated with "reference blood glucose" obtained from a tail vein sample. See the Moatti-Sirat publication, page 225. The correlation between the glucose concentration values measured by the device and the reference sensor is depicted in FIG. 6 (reproduced below) and described on page 227.

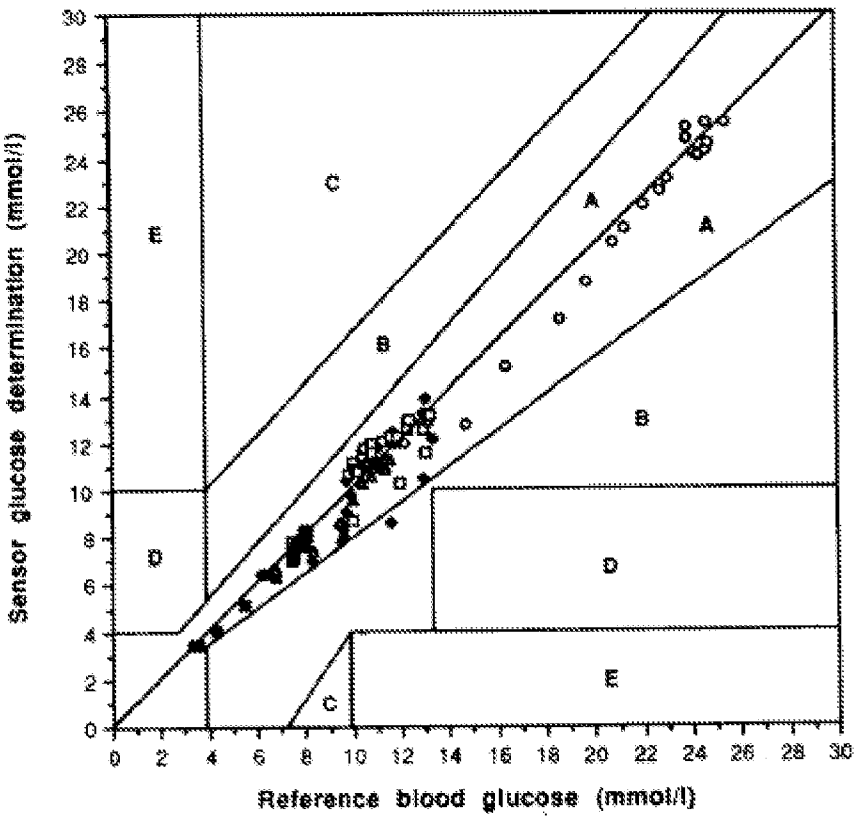

Fig. 6. Error grid analysis for estimation of the accuracy of sensor generated blood glucose values, ten days after implantation

As shown in FIG. 6, and described on page 227, 100 of 101 (i.e., 99%) of the experimental values fall within Zone A, which deviates no more than 20% from the reference. In other words, 99% of glucose concentration values measured by the signal are within 20% of one or more reference values. As such, the sensor/membrane combination described and tested in the Moatti-Sirat publication meets the claimed accuracy standard of "at least 95% of glucose concentration values measured by the device are within 25% of corresponding values determined by analysis of blood over the period of time."

Accordingly, one of skill in the art would understand how to modify the sensor of the Kusano publication by including the sensor/membrane combination described and tested in the Moatti-Sirat publication and arrive at the features of claim 94. Such a modification of the Kusano publication would simply be a combination of prior art elements according to their established functions, as noted above, and would be within the capabilities of a person having ordinary skill in the art.

10. Dependent Claim 99

As outlined above, claim 80 is anticipated by the Kusano publication. The features of claim 99, which depends from claim 80, are taught by the Moatti-Sirat publication. One of skill in the art would understand how to modify the teachings of the Kusano publication, in view of the Moatti-Sirat publication, to meet the features of claim 99. As such, claim 99 would be obvious under 35 U.S.C. § 103.

> Claim 99. The device of claim 80, wherein the period of time is at least about 3 days.

The Moatti-Sirat publication teaches a device (e.g., miniaturized glucose sensor) comprising electrodes configured for implantation in a subcutaneous tissue of the host for at least 10 days. See, for example, the Moatti-Sirat publication, Summary, and pgs. 224 and 228.

11. Dependent Claim 100

As outlined above, claim 80 is anticipated by the Kusano publication. The features of claim 100, which depends from claim 80, are taught by the Moatti-Sirat publication. One of skill in the art would understand how to modify the teachings of the Kusano publication, in view of the Moatti-Sirat publication, to meet the features of claim 100. As such, claim 100 would be obvious under 35 U.S.C. § 103.

> Claim 100. The device of claim 80, wherein the period of time is at least about 5 days.

The Moatti-Sirat publication teaches a device (e.g., miniaturized glucose sensor) comprising electrodes configured for implantation in a subcutaneous tissue of the host for at least 10 days. See, for example, the Moatti-Sirat publication, Summary, and pgs. 224 and 228.

12. Dependent Claim 101

As outlined above, claim 80 is anticipated by the Kusano publication. The features of claim 101, which depends from claim 80, are taught by the Moatti-Sirat publication. One of skill in the art would understand how to modify the teachings of the Kusano publication, in view of the Moatti-Sirat publication, to meet the features of claim 101. As such, claim 101 would be obvious under 35 U.S.C. § 103.

> Claim 101. The device of claim 80, wherein the period of time is at least about 7 days.

The Moatti-Sirat publication teaches a device (e.g., miniaturized glucose sensor) comprising electrodes configured for implantation in a subcutaneous tissue of the host for at least 10 days. See, for example, the Moatti-Sirat publication, Summary, and pgs. 224 and 228.

13. Dependent Claim 120

As outlined above, claim 107 is anticipated by the Kusano publication. The features of claim 120, which depends from claim 107, are taught by the Moatti-Sirat publication. One of skill in the art would understand how to modify the teachings of the Kusano publication, in view of the Moatti-Sirat publication, to meet the features of claim 120. As such, claim 120 would be obvious under 35 U.S.C. § 103.

> Claim 120. The device of claim 107, wherein at least 95% of glucose concentration values measured by the device are within 25% of corresponding values determined by analysis of blood over the period of time.

The Moatti-Sirat publication teaches a glucose sensor for implantation in the subcutaneous tissue of an animal. See the Moatti-Sirat publication, Summary, pg. 224. The Moatti-Sirat publication teaches a membrane disposed over the glucose sensor. See the Moatti-Sirat publication, pg. 225. Further, page 225 and Table 1 of the Moatti-Sirat publication teaches that the electrode is configured to measure a current produced by the electrode with substantial linearity up to a glucose concentration of 22 mM (i.e., 400 mg/dL).

With regard to the claimed accuracy of the device of claim 120, The Moatti-Sirat publication uses the EGA of the Clark publication to present its experimental results. The experimental results of the Moatti-Sirat publication, in turn, fall within the accuracy standard called for in claim 120. For example, the Moatti-Sirat publication teaches that subcutaneous glucose concentrations determined by an implanted sensor are correlated with "reference blood glucose" obtained from a tail vein sample. See the Moatti-Sirat publication, page 225. The correlation between the glucose concentration values measured by the device and the reference sensor is depicted in FIG. 6 (reproduced below) and described on page 227.

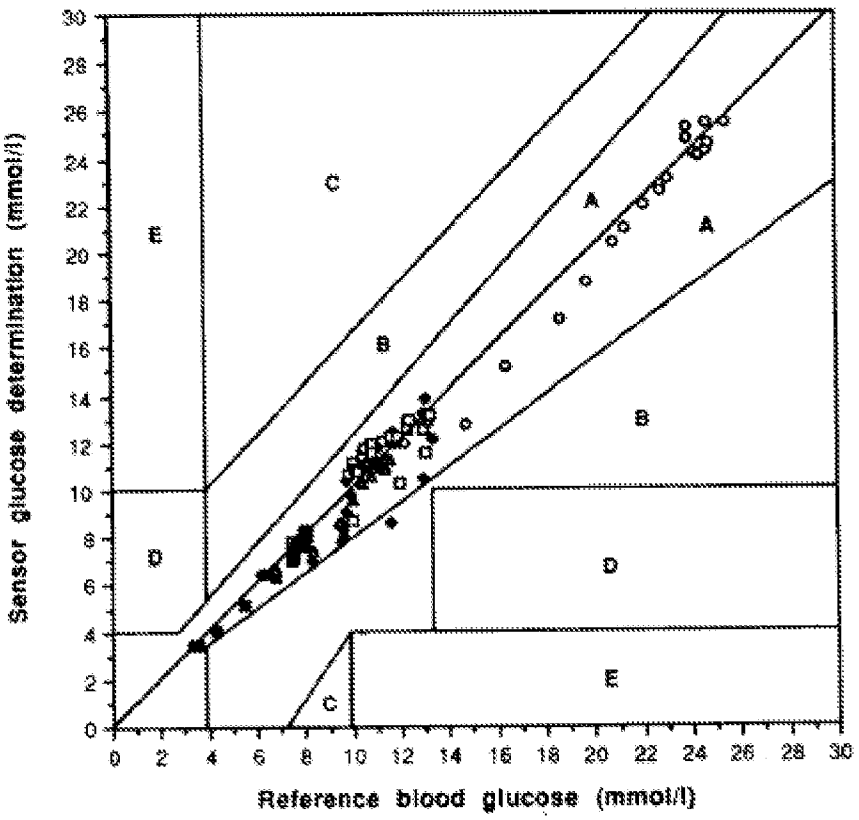

Fig. 6. Error grid analysis for estimation of the accuracy of sensor generated blood glucose values, ten days after implantation

As shown in FIG. 6, and described on page 227, 100 of 101 (i.e., 99%) of the experimental values fall within Zone A, which deviates no more than 20% from the reference. In other words, 99% of glucose concentration values measured by the signal are within 20% of one or more reference values. As such, the sensor/membrane combination described and tested in the Moatti-Sirat publication meets the claimed accuracy standard of "at least 95% of glucose concentration values measured by the device are within 25% of corresponding values determined by analysis of blood over the period of time."

Accordingly, one of skill in the art would understand how to modify the sensor of the Kusano publication by including the sensor/membrane combination described and tested in the Moatti-Sirat publication and arrive at the features of claim 120. Such a modification of the Kusano publication would simply be a combination of prior art elements according to their established functions, as noted above, and would be within the capabilities of a person having ordinary skill in the art.

14. Dependent Claim 125

As outlined above, claim 107 is anticipated by the Kusano publication. The features of claim 125, which depends from claim 107, are taught by the Moatti-Sirat publication. One of skill in the art would understand how to modify the teachings of the Kusano publication, in view of the Moatti-Sirat publication, to meet the features of claim 125. As such, claim 125 would be obvious under 35 U.S.C. § 103.

> Claim 125. The device of claim 107, wherein the period of time is at least about 3 days.

The Moatti-Sirat publication teaches a device (e.g., miniaturized glucose sensor) comprising electrodes configured for implantation in a subcutaneous tissue of the host for at least 10 days. See, for example, the Moatti-Sirat publication, Summary, and pgs. 224 and 228.

15. Dependent Claim 126

As outlined above, claim 107 is anticipated by the Kusano publication. The features of claim 126, which depends from claim 107, are taught by the Moatti-Sirat publication. One of skill in the art would understand how to modify the teachings of the Kusano publication, in view of the Moatti-Sirat publication, to meet the features of claim 126. As such, claim 126 would be obvious under 35 U.S.C. § 103.

> Claim 126. The device of claim 107, wherein the period of time is at least about 5 days.

The Moatti-Sirat publication teaches a device (e.g., miniaturized glucose sensor) comprising electrodes configured for implantation in a subcutaneous tissue of the host for at least 10 days. See, for example, the Moatti-Sirat publication, Summary, and pgs. 224 and 228.

16. Dependent Claim 127

As outlined above, claim 107 is anticipated by the Kusano publication. The features of claim 127, which depends from claim 107, are taught by the Moatti-Sirat publication. One of skill in the art would understand how to modify the teachings of the Kusano publication, in view of the Moatti-Sirat publication, to meet the features of claim 127. As such, claim 127 would be obvious under 35 U.S.C. § 103.

> Claim 127. The device of claim 107, wherein the period of time is at least about 7 days.

The Moatti-Sirat publication teaches a device (e.g., miniaturized glucose sensor) comprising electrodes configured for implantation in a subcutaneous tissue of the host for at least 10 days. See, for example, the Moatti-Sirat publication, Summary, and pgs. 224 and 228.

I. Claims 52, 77, 104, and 130 are obvious under 35 U.S.C. § 103 in view of the Kusano publication and the Csöregi publication.

Claims 52, 77, 104, and 130 are unpatentable under 35 U.S.C. § 103(a) over the Kusano publication in view of the Csöregi publication. Sections VI.I.1 – VI.I.4 detail how claims 52, 77, 104, and 130 are rendered obvious by the combination of the Kusano publication and the Csöregi publication. For the examiner's convenience, the arguments presented herein are summarized in the table provided in **Exhibit P**.

1. Dependent Claim 52

As outlined above, claim 28 is anticipated by the Kusano publication. The features of claim 52, which depends from claim 28, are taught by the Csöregi publication. One of skill in the art would understand how to modify the teachings of the Kusano publication, in view of the Csöregi publication, to meet the features of claim 52. As such, claim 52 would be obvious under 35 U.S.C. § 103.

> Claim 52. The device of claim 28, wherein the device is configured for single-point recalibration.

The Csöregi publication teaches a device for measuring glucose concentration in a host. See the Csöregi publication, Abstract. The sensors of the Csöregi publication are configured for single-point recalibration. Specifically, the Csöregi publication states:

> The stability observed and the existence of a valid zero point in the presence of interferants suggested that the sensor could be used in vivo for 72 h and be tested/recalibrated in vivo through a single-point calibration, i.e., by withdrawing only a single sample of blood for independent analysis.

The Csöregi publication, pg. 3136.

Accordingly, one of skill in the art would understand how to modify the sensor of the Kusano publication by configuring the sensor for single point recalibration as described in the

Csöregi publication and arrive at the features of claim 52. Such a modification of the Kusano publication would simply be a combination of prior art elements according to their established functions, as noted above, and would be within the capabilities of a person having ordinary skill in the art.

2. Dependent Claim 77

As outlined above, claim 53 is anticipated by the Kusano publication. The features of claim 77, which depends from claim 53, are taught by the Csöregi publication. One of skill in the art would understand how to modify the teachings of the Kusano publication, in view of the Csöregi publication, to meet the features of claim 77. As such, claim 77 would be obvious under 35 U.S.C. § 103.

> Claim 77. The device of claim 53, wherein the device is configured for single-point recalibration.

The Csöregi publication teaches a device for measuring glucose concentration in a host. See the Csöregi publication, Abstract. The sensors of the Csöregi publication are configured for single-point recalibration. Specifically, the Csöregi publication states:

> The stability observed and the existence of a valid zero point in the presence of interferants suggested that the sensor could be used in vivo for 72 h and be tested/recalibrated in vivo through a single-point calibration, i.e., by withdrawing only a single sample of blood for independent analysis.

The Csöregi publication, pg. 3136.

Accordingly, one of skill in the art would understand how to modify the sensor of the Kusano publication by configuring the sensor for single point recalibration as described in the Csöregi publication and arrive at the features of claim 77. Such a modification of the Kusano publication would simply be a combination of prior art elements according to their established functions, as noted above, and would be within the capabilities of a person having ordinary skill in the art.

3. Dependent Claim 104

As outlined above, claim 80 is anticipated by the Kusano publication. The features of claim 104, which depends from claim 80, are taught by the Csöregi publication. One of skill in the art would understand how to modify the teachings of the Kusano publication, in view of the

Csöregi publication, to meet the features of claim 104. As such, claim 104 would be obvious under 35 U.S.C. § 103.

> Claim 104. The device of claim 80, wherein the device is configured for single-point recalibration.

The Csöregi publication teaches a device for measuring glucose concentration in a host. See the Csöregi publication, Abstract. The sensors of the Csöregi publication are configured for single-point recalibration. Specifically, the Csöregi publication states:

> The stability observed and the existence of a valid zero point in the presence of interferants suggested that the sensor could be used in vivo for 72 h and be tested/recalibrated in vivo through a single-point calibration, i.e., by withdrawing only a single sample of blood for independent analysis.

The Csöregi publication, pg. 3136.

Accordingly, one of skill in the art would understand how to modify the sensor of the Kusano publication by configuring the sensor for single point recalibration as described in the Csöregi publication and arrive at the features of claim 104. Such a modification of the Kusano publication would simply be a combination of prior art elements according to their established functions, as noted above, and would be within the capabilities of a person having ordinary skill in the art.

4. Dependent Claim 130

As outlined above, claim 107 is anticipated by the Kusano publication. The features of claim 130, which depends from claim 107, are taught by the Csöregi publication. One of skill in the art would understand how to modify the teachings of the Kusano publication, in view of the Csöregi publication, to meet the features of claim 130. As such, claim 130 would be obvious under 35 U.S.C. § 103.

> Claim 130. The device of claim 107, wherein the device is configured for single-point recalibration.

The Csöregi publication teaches a device for measuring glucose concentration in a host. See the Csöregi publication, Abstract. The sensors of the Csöregi publication are configured for single-point recalibration. Specifically, the Csöregi publication states:

> The stability observed and the existence of a valid zero point in the presence of interferants suggested that the sensor could be used in vivo for 72 h and be tested/recalibrated in vivo through a single-point calibration, i.e., by withdrawing only a single sample of blood for independent analysis.

The Csöregi publication, pg. 3136.

Accordingly, one of skill in the art would understand how to modify the sensor of the Kusano publication by configuring the sensor for single point recalibration as described in the Csöregi publication and arrive at the features of claim 130. Such a modification of the Kusano publication would simply be a combination of prior art elements according to their established functions, as noted above, and would be within the capabilities of a person having ordinary skill in the art.

VII. CERTIFICATION OF SERVICE (37 C.F.R. § 1.510(b)(5))

The United States Patent and Trademark Office records indicate that the Shults '562 patent is presently assigned to DexCom, Inc. (see Assignment recorded at Reel/Frame: 023891/0316). The undersigned certifies that the request for *ex parte* reexamination has been served by Federal Express, deposited on January 31, 2011, on the patent owner at the correspondence address provided in the USPTO PAIR system:

KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE CA 92614

VIII. STATEMENT OF AUTHORITY TO ACT ON BEHALF OF THE REAL PARTY IN INTEREST PURSUANT TO 37 C.F.R. § 1.34

The undersigned states that he is acting on behalf of the Requestor, Abbott Diabetes Care Inc., in a representative capacity pursuant to 37 C.F.R. § 1.34.

IX. CONCLUSION

For the reasons given above, reexamination of claims 1, 5, 9, 15, 20-22, 25-28, 32, 36, 42, 47-49, 52, 53, 57, 61, 67, 72-74, 77-80, 84, 88, 94, 99-101, 104-107, 111, 120, 125-127, and 130-132 of U.S. Patent No. 7,792,562 is respectfully requested.

The USPTO is directed and authorized to charge all Requestor's required fees associated with the Request to Deposit Account No. 50-0815, order number ADCI-GEN50, as well as credit any overpayments to said Deposit Account.

Respectfully submitted,
BOZICEVIC, FIELD & FRANCIS LLP

Date: January 31, 2011

By: /Peter A. Socarras, Reg. No. 54,457/
Peter Alexander Socarras
Attorney for Requester
Registration No. 54,457

Date: January 31, 2011

By: /Edward J. Baba, Reg. No. 52,581/
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XI. EXHIBIT LIST

Exhibit No.	Description
Exhibit A	U.S. Patent No. 7,792,562 to Shults *et al.*, issued on September 7, 2010.
Exhibit B	U.S. Patent No. 5,322,063 to Allen *et al.*, issued on June 21, 1994.
Exhibit C	Kusano, H., Glucose enzyme electrode with percutaneous interface which operates independently of dissolved oxygen, *Clin. Phys. Physiol. Meas.*, vol. 10, 1:1-9 (1989).
Exhibit D	Mastrototaro *et al.*, "An electroenzymatic glucose sensor fabricated on a flexible substrate," *Sensors and Actuators B*, 5:139-44 (1991).
Exhibit E	Moatti-Sirat *et al.*, Towards continuous glucose monitoring: in vivo evaluation of a miniaturized glucose sensor implanted for several days in rat subcutaneous tissue, *Diabetologia*, 35:224-230 (1992).
Exhibit F	Clarke *et al.*, Evaluating Clinical Accuracy of Systems for Self-Monitoring of Blood Glucose, *Diabetes Care*, Vol. 10, No. 5:622-628 (1987).
Exhibit G	Csöregi *et al.*, Design, Characterization, and One-Point in Vivo Calibration of a Subcutaneously Implanted Glucose Electrode, *Analytical Chemistry*, 66(19):3131-3138 (October 1, 1994).
Exhibit H	Table illustrating that each element of claims 1, 5, 9, 20, 26-28, 32, 36, 47, 53, 57, 61, 72, 78-80, 84, 88, 99, 105-107, 111, 125, 131, and 132 is provided by the Allen '063 patent.
Exhibit I	Table illustrating that each element of claims 15, 21, 22, 42, 48, 49, 67, 73, 74, 94, 100, 101, 120, 126, and 127 is provided by the Allen '063 patent in view of the Moatti-Sirat publication.
Exhibit J	Table illustrating that each element of claims 25, 52, 77, 104, and 130 is provided by the Allen '063 patent in view of the Csöregi publication.
Exhibit K	Table illustrating that each element of claims 1, 5, 9, 26, and 27 is provided by the Kusano publication in view of the Mastrototaro publication.
Exhibit L	Table illustrating that each element of claims 15 and 20-22 is provided by the Kusano publication in view of the Mastrototaro publication, and further in view of the Moatti-Sirat publication.
Exhibit M	Table illustrating that each element of claim 25 is provided by the Kusano publication in view of the Mastrototaro publication, and further in view of the Csöregi publication.
Exhibit N	Table illustrating that each element of claims 28, 32, 36, 53, 57, 61, 78-80, 84, 88, 105-107, 111, 131, and 132 is provided by the Kusano publication.
Exhibit O	Table illustrating that each element of claims 42, 47-49, 67, 72-74, 94, 99-101, 120, and 125-127 is provided by the Kusano publication in view of the Moatti-Sirat publication.
Exhibit P	Table illustrating that each element of claims 52, 77, 104, and 130 is provided by the Kusano publication in view of the Csöregi publication.

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	
Filing Date	2011-01-31
First Named Inventor	Shults, Mark C.
Art Unit	
Examiner Name	
Attorney Docket Number	ADCI-GEN50

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	1	5322063		1994-06-21	Allen et al.	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	2011-01-31
	First Named Inventor	Shults, Mark C.
	Art Unit	
	Examiner Name	
	Attorney Docket Number	ADCI-GEN50

	1	Kusano, H., Glucose enzyme electrode with percutaneous interface which operates independently of dissoled oxygen, Clin. Phys. Physiol. Meas., vol. 10, 1:1-9 (1989).	☐
	2	Mastrototaro et al., "An electroenzymatic glucose sensor fabricated on a flexible substrate," Sensors and Actuators B, 5:139-44 (1991).	☐
	3	Moatti-Sirat et al., Towards continuous glucose monitoring: in vivo evaluation of a miniaturized glucose sensor implanted for several days in rat subcutaneous tissue, Diabetologia, 35:224-230 (1992).	☐
	4	Clarke et al., Evaluating Clinical Accuracy of Systems for Self-Monitoring of Blood Glucose, Diabetes Care, Vol. 10, No. 5:622-628 (1987).	☐
	5	Csöregi et al., Design, Characterization, and One-Point in Vivo Calibration of a Subcutaneously Implanted Glucose Electrode, Analytical Chemistry, 66(19):3131-3138 (October 1, 1994).	☐

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EXAMINER SIGNATURE

Examiner Signature		Date Considered	

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[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	2011-01-31
	First Named Inventor	Shults, Mark C.
	Art Unit	
	Examiner Name	
	Attorney Docket Number	ADCI-GEN50

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Edward J. Baba, Reg. No. 52,581/	Date (YYYY-MM-DD)	2011-01-31
Name/Print	Edward J. Baba	Registration Number	52,581

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

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7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.